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Hee-Hanson et al.

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(54) **INJECTOR DEVICE**

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(22) Filed: **Mar. 4, 2024**

(51) **Int. Cl.**
A61M 5/32 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 5/3243*** (2013.01); ***A61M 5/3202*** (2013.01); ***A61M 5/3245*** (2013.01); *A61M 2205/0216* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2205/0216; A61M 5/3202; A61M 5/3205; A61M 5/321; A61M 5/3243; A61M 5/3245; A61M 5/3275
See application file for complete search history.

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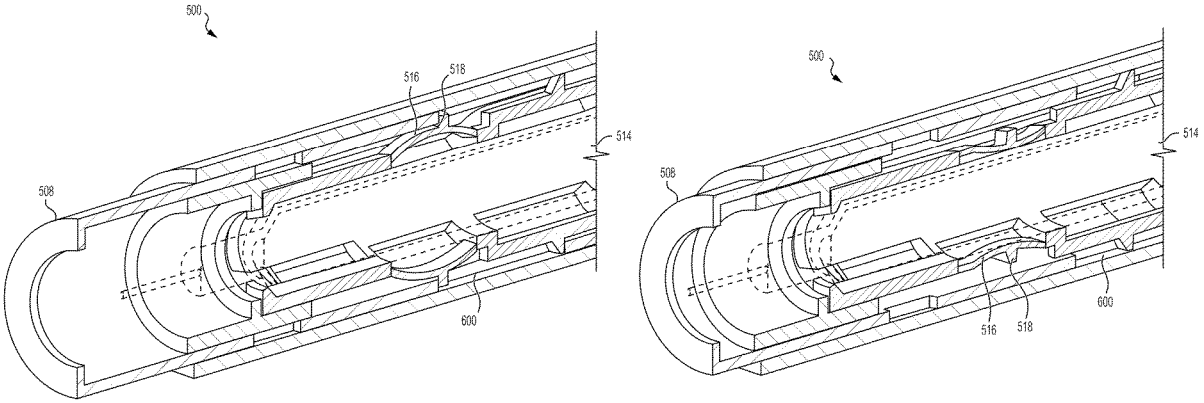
(57) **ABSTRACT**

A medicament delivery device for reducing a force required to activate the device includes a needle disposed at a distal end of the device, a needle cover, and a body. The needle cover is axially movable relative to the body between an initial position in which the needle cover covers the needle and an activated position for dispensing a medicament. The needle protrudes from a distal end of the needle cover when the needle cover is in the activated position. The medicament delivery device includes a carrier configured to support a syringe. The carrier is disposed within the needle cover and includes a deformable element configured to change from a first configuration in which the deformable element is engaged with the needle cover to a second configuration in which the deformable element is not engaged with the needle cover.

21 Claims, 15 Drawing Sheets



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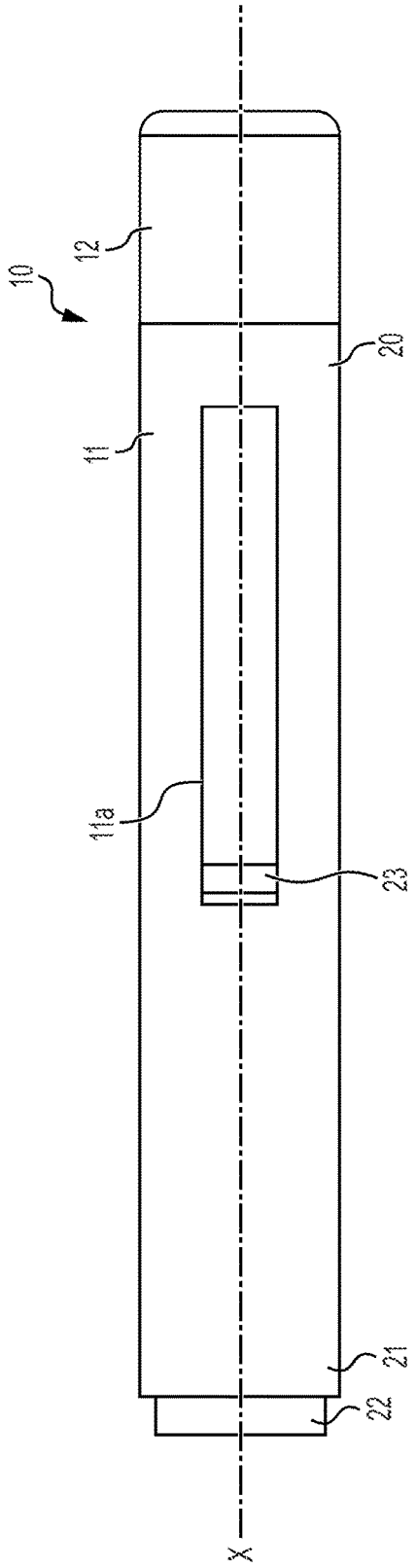


FIG. 1A

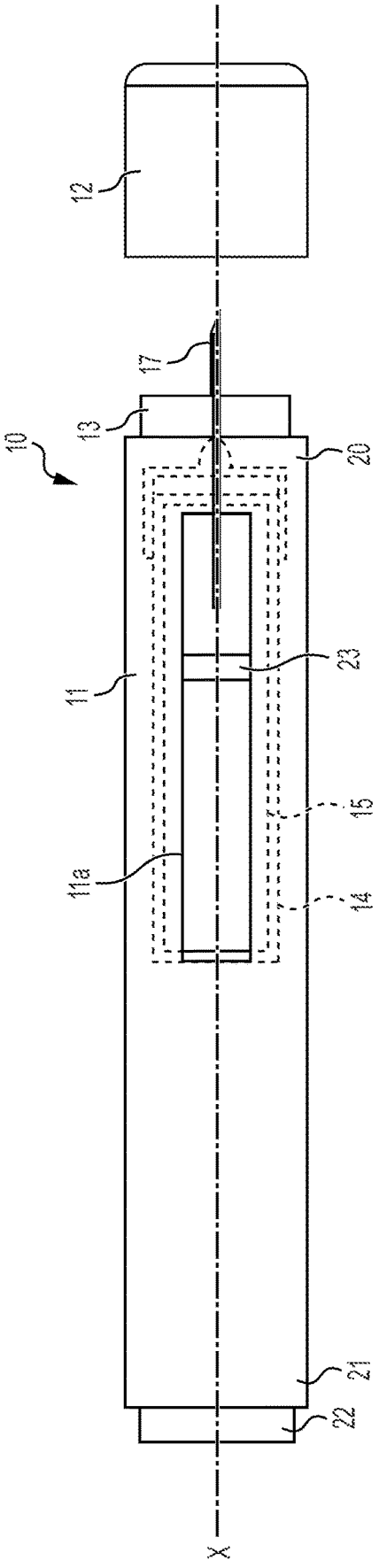


FIG. 1B

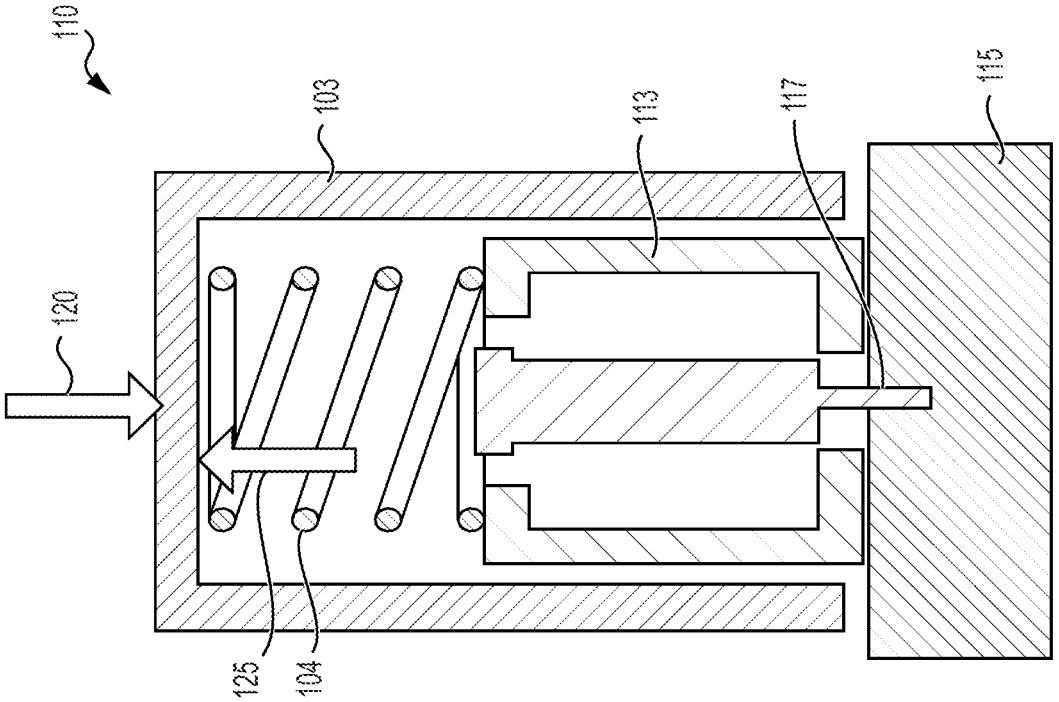


FIG. 2B

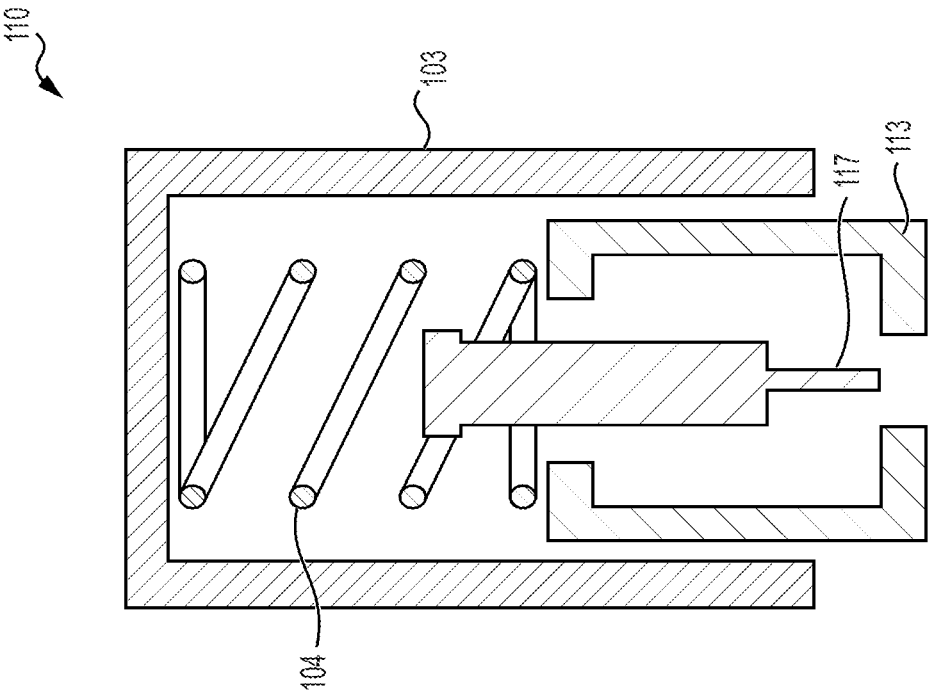


FIG. 2A

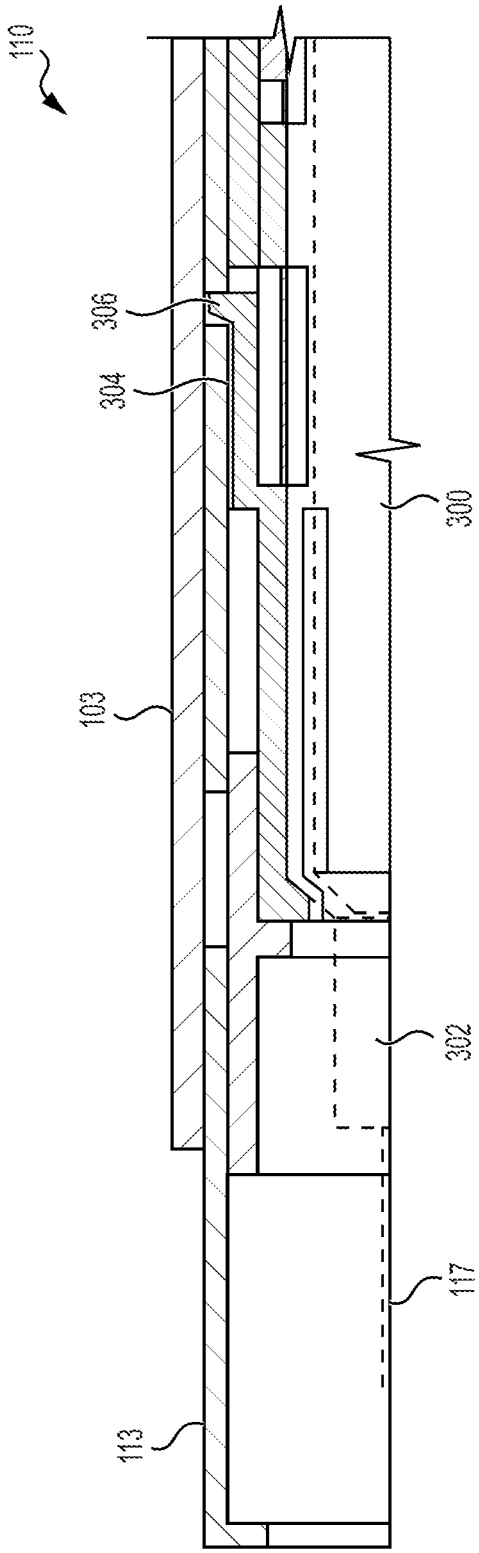


FIG. 3A

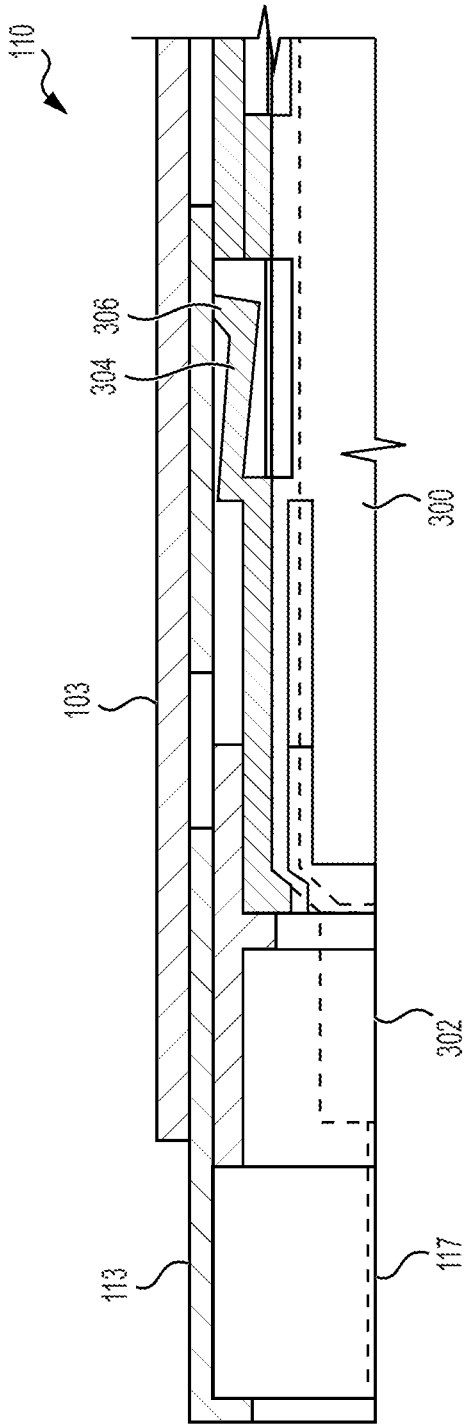


FIG. 3B

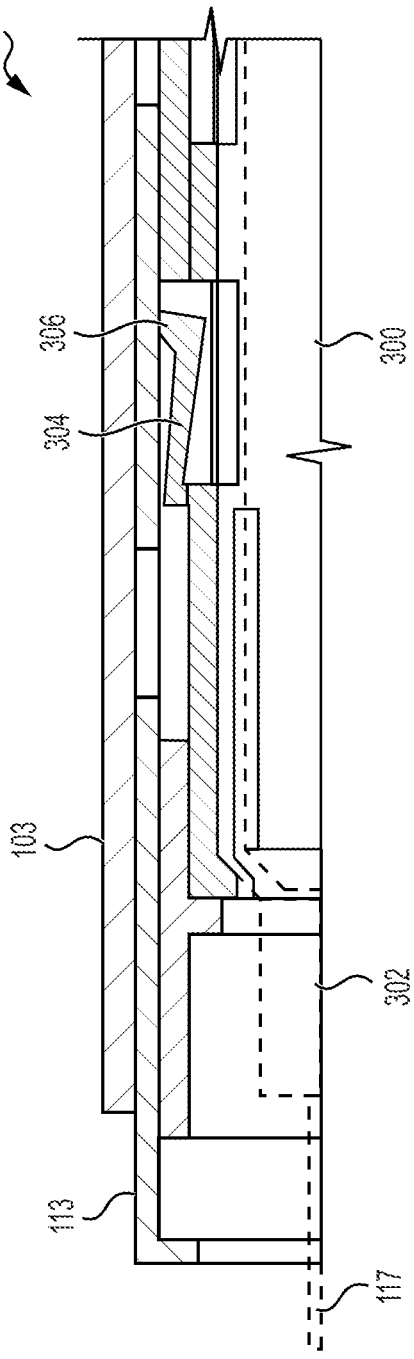


FIG. 3C

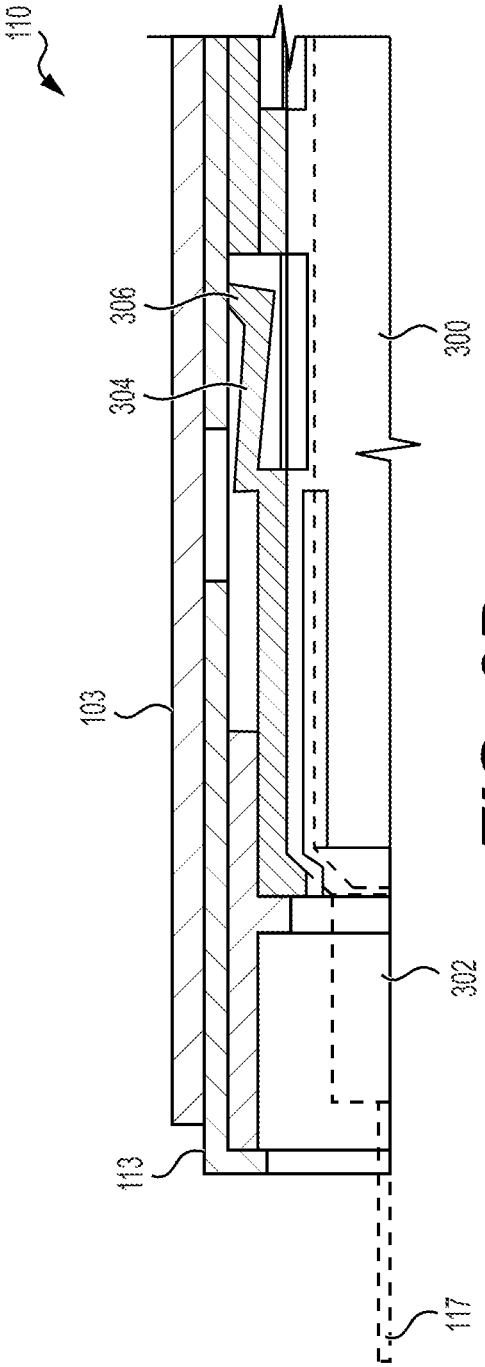
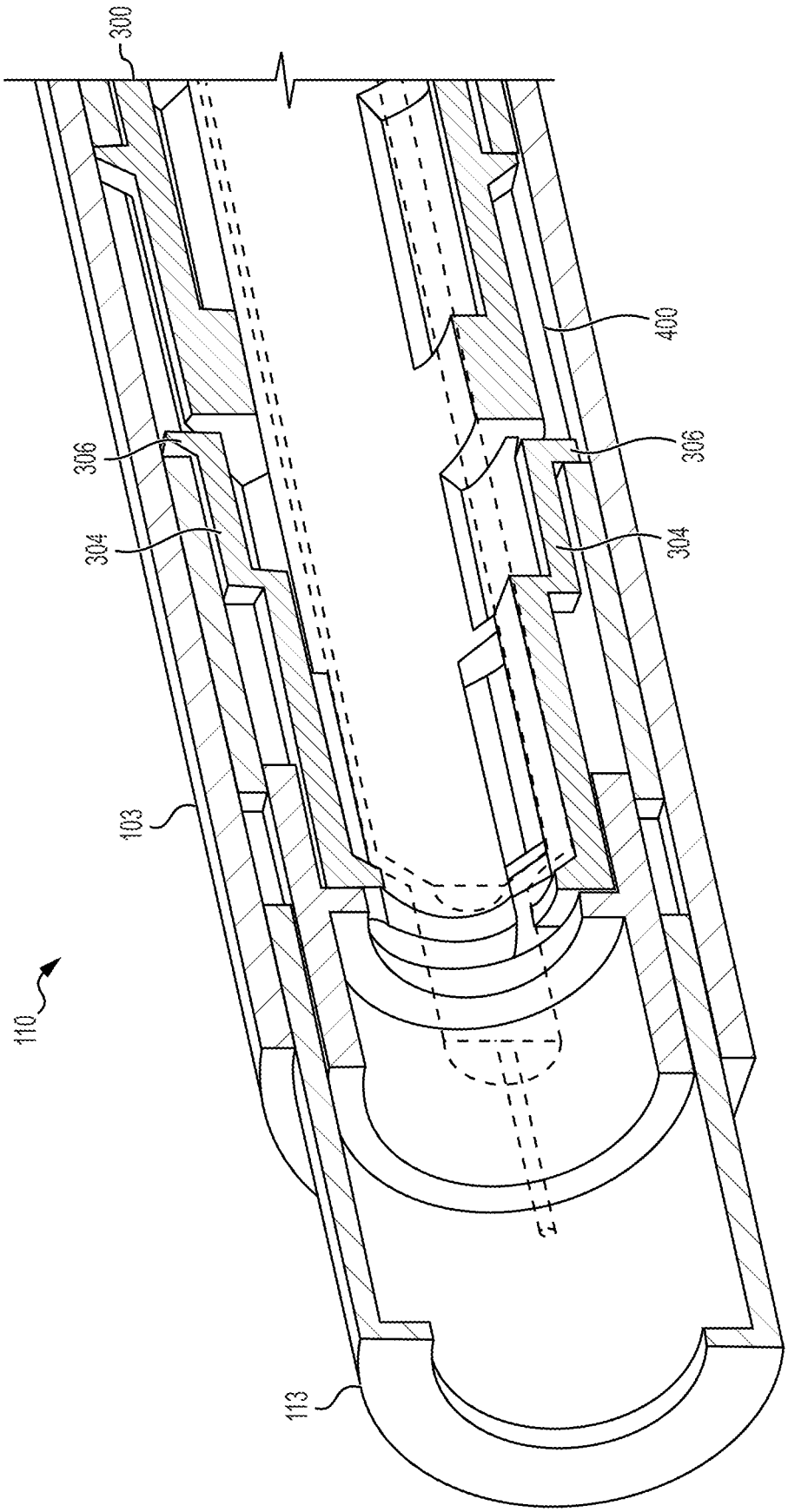


FIG. 3D



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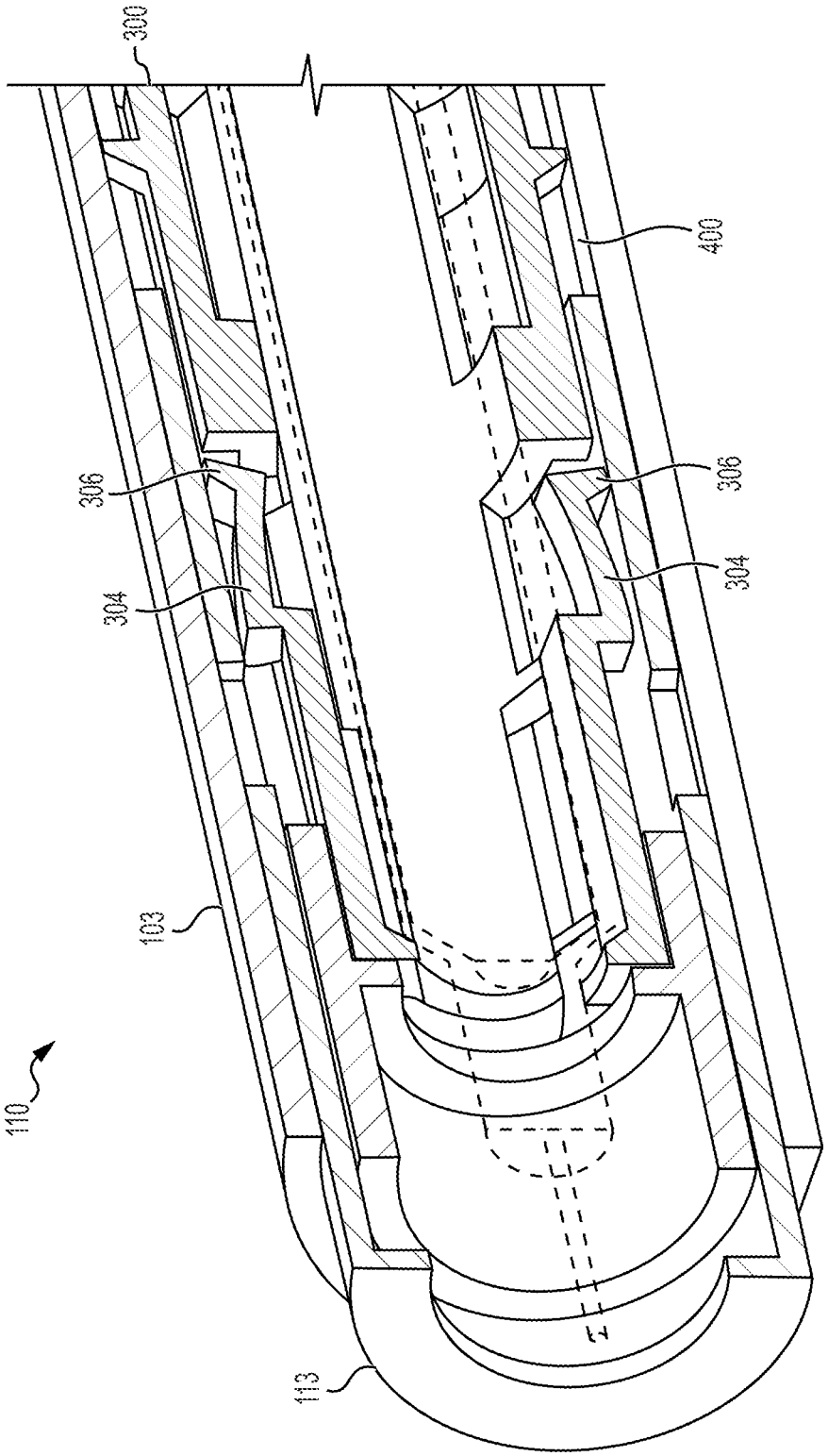

FIG. 4B

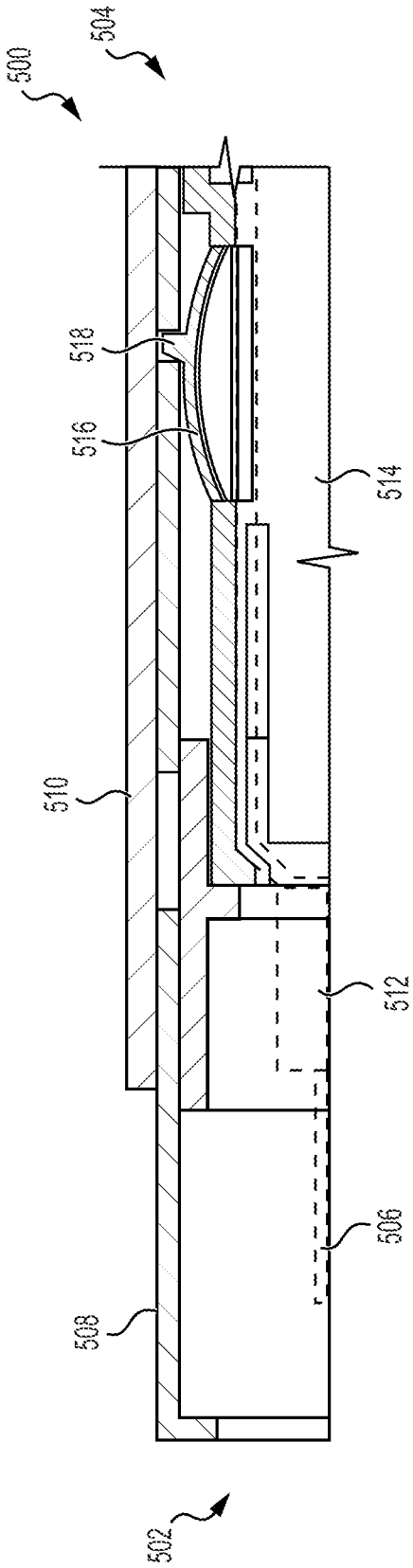
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FIG. 5A

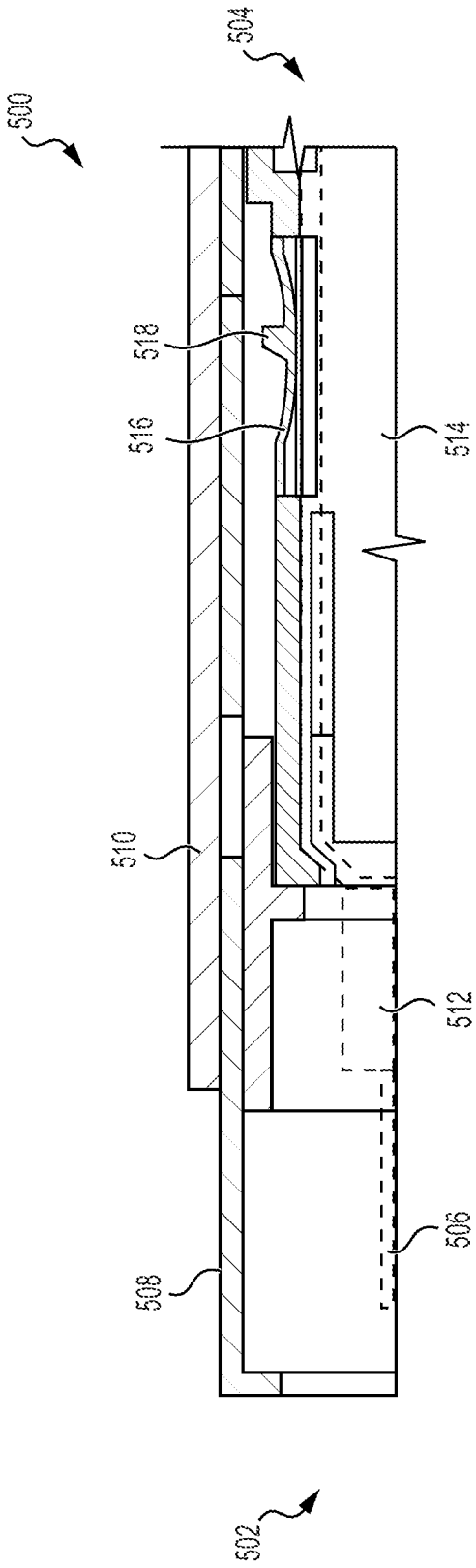
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FIG. 5B

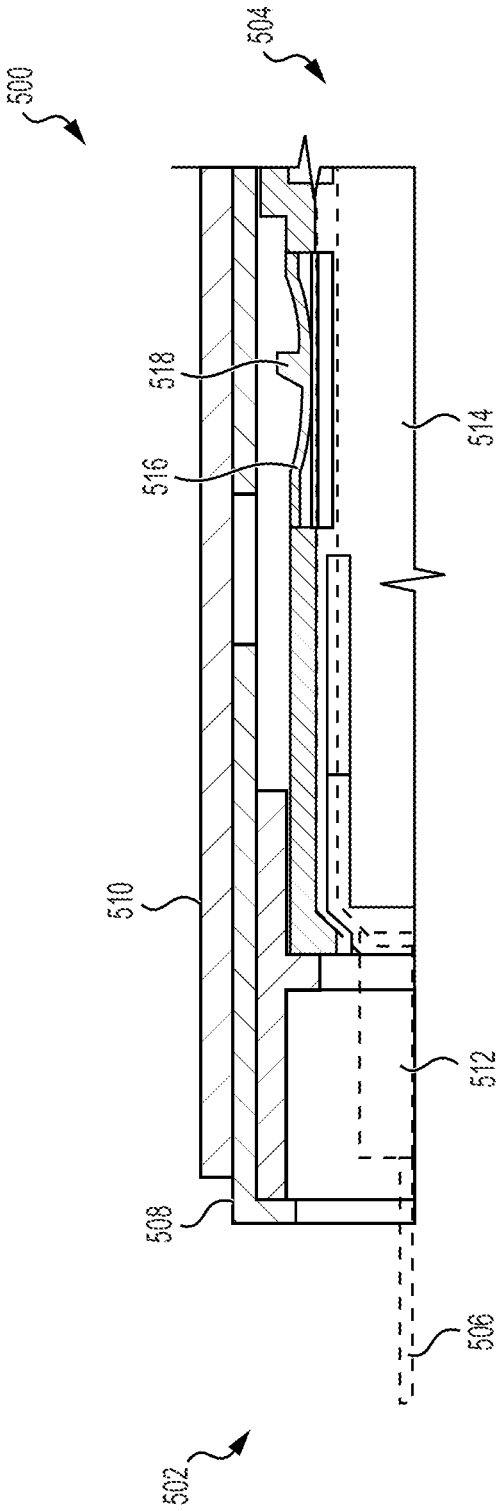

FIG. 5C

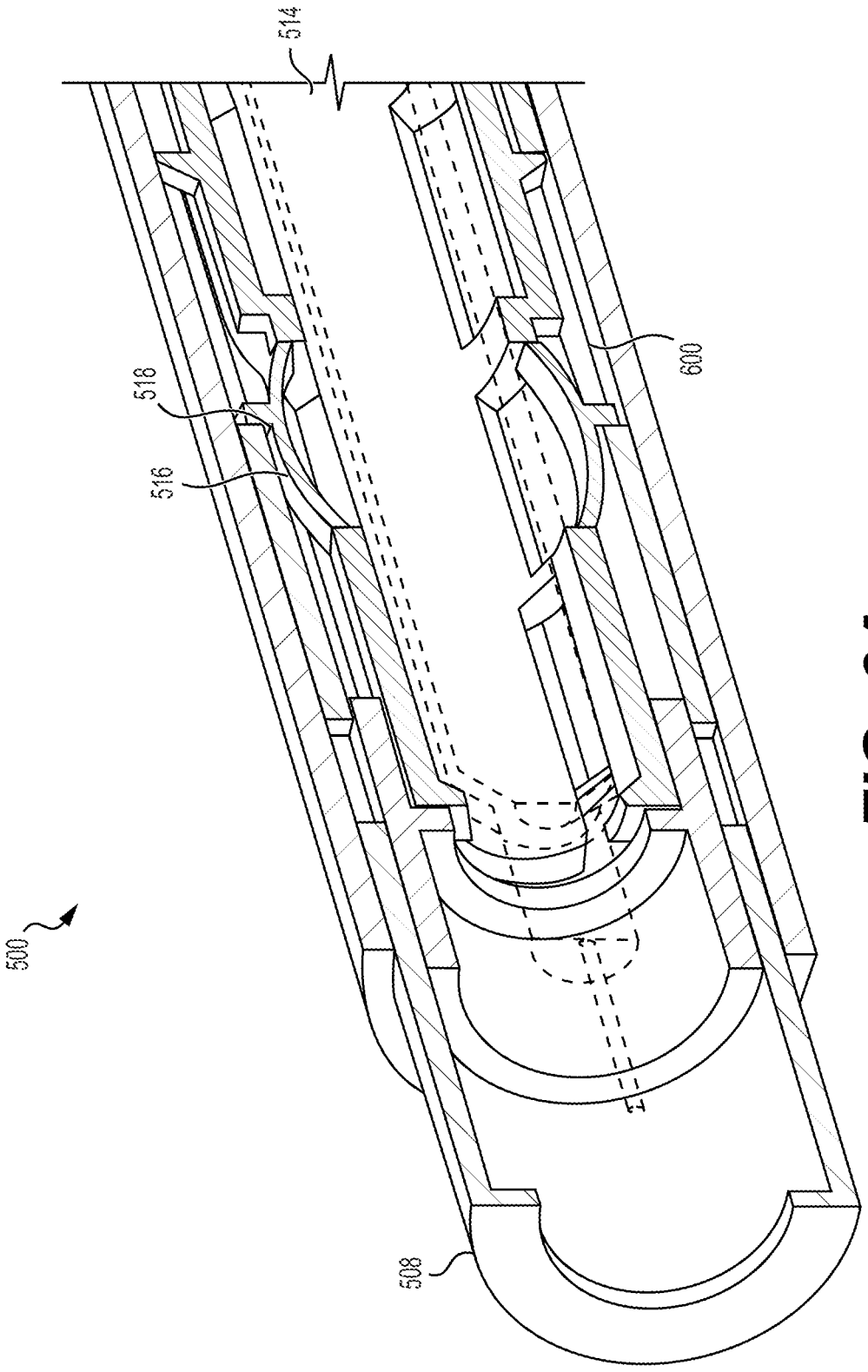

FIG. 6A

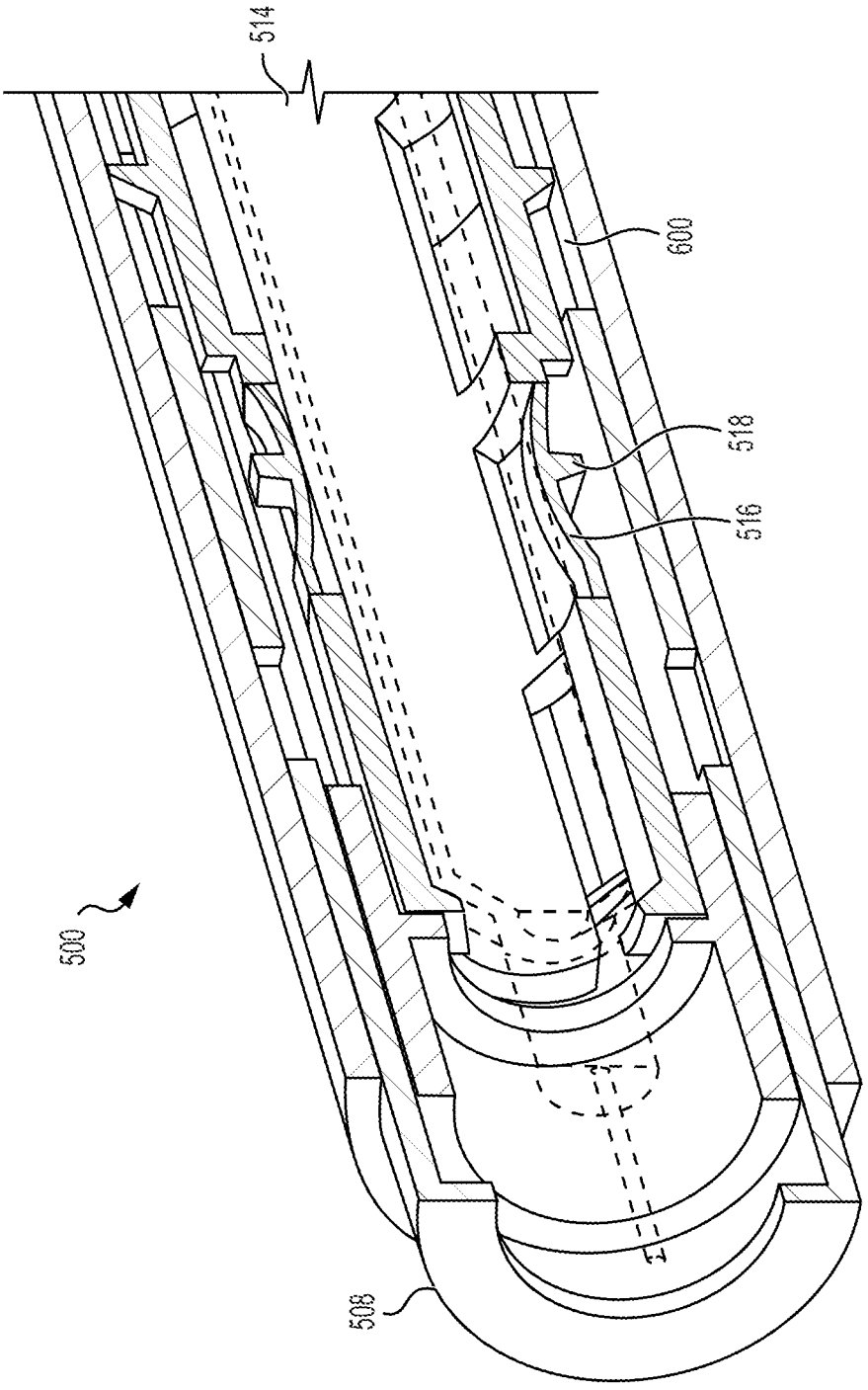

FIG. 6B

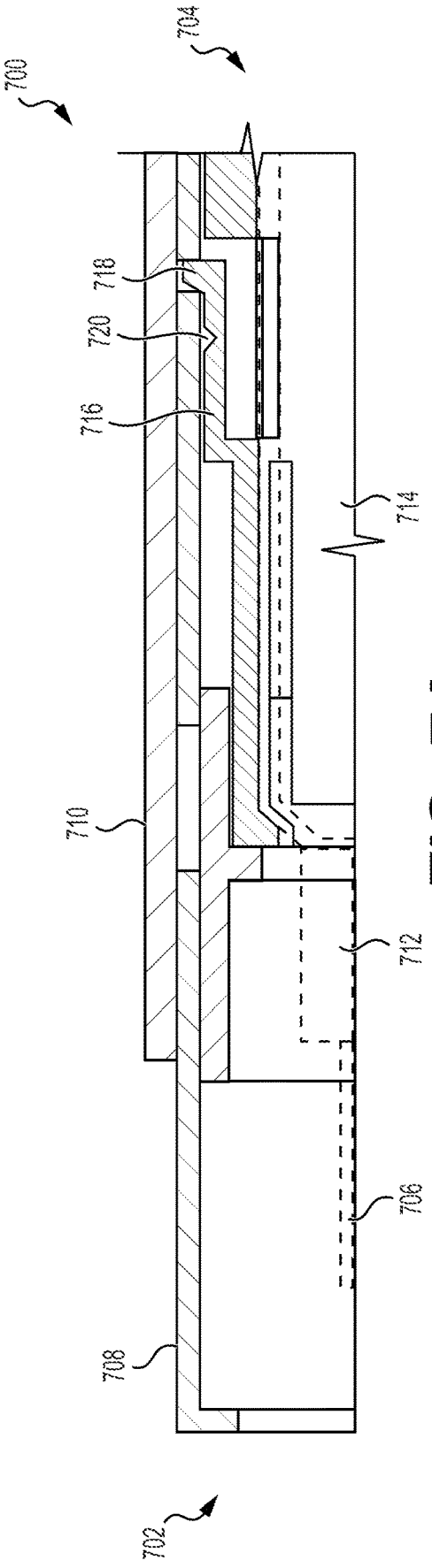
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FIG. 7A

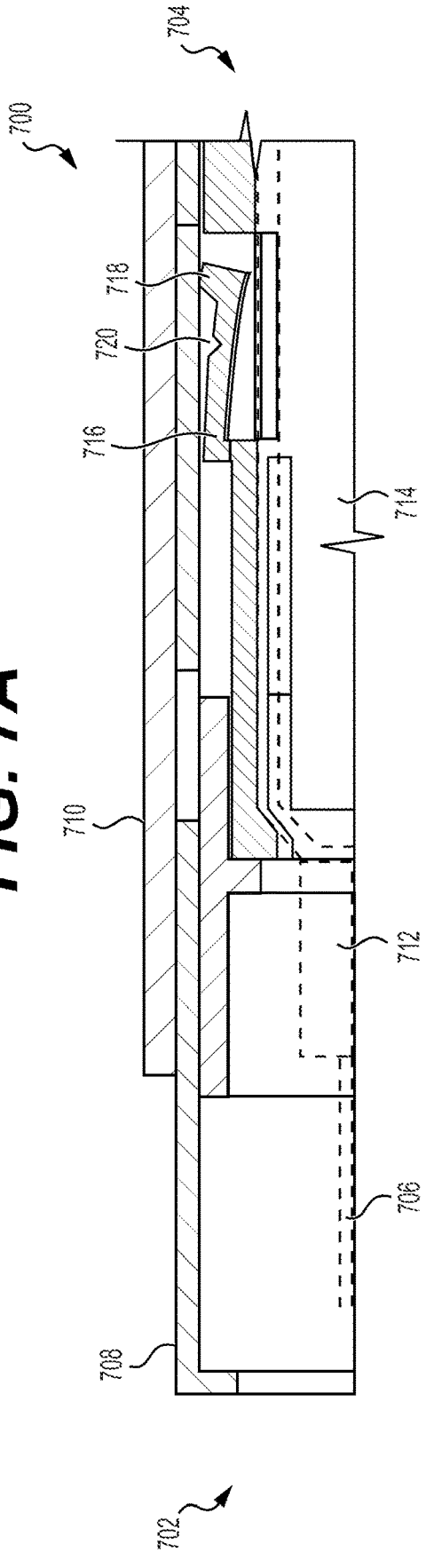
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FIG. 7B

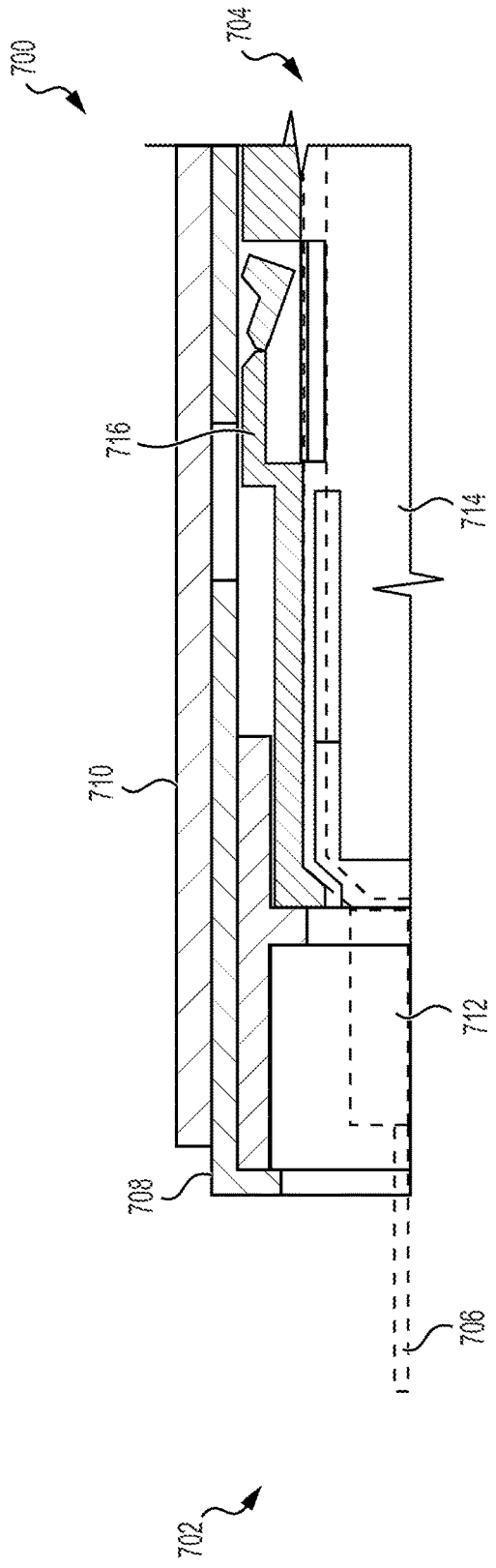
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FIG. 7C

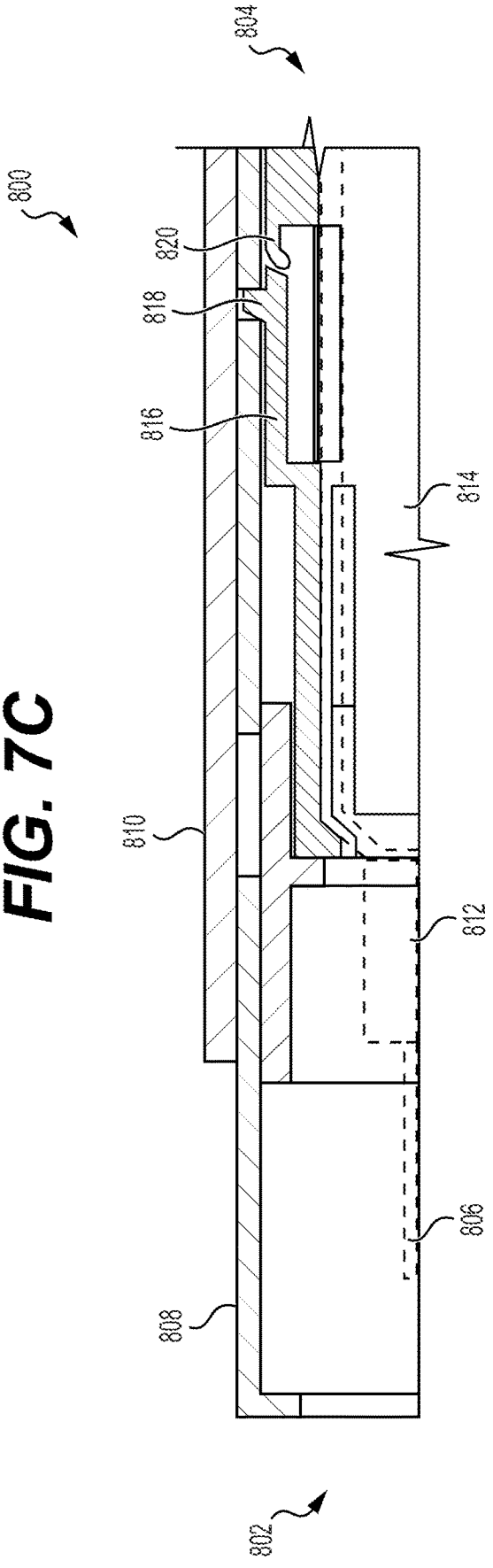
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FIG. 8A

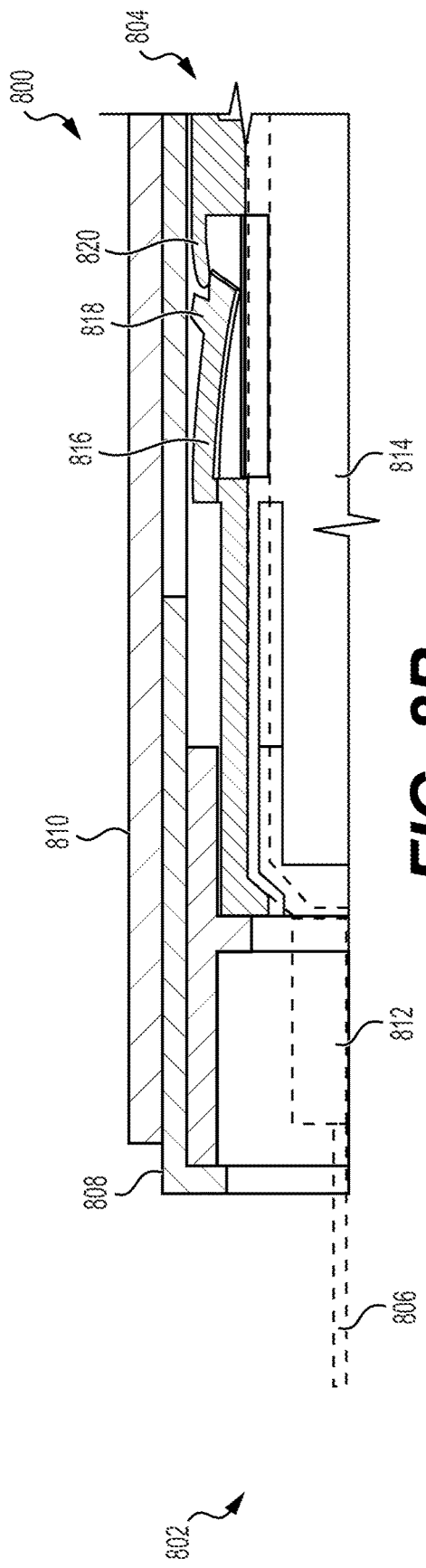

FIG. 8B

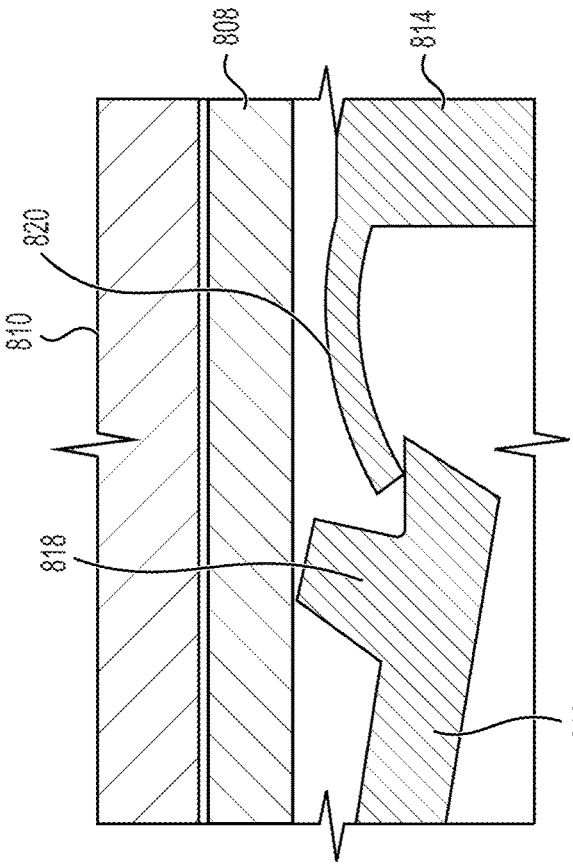

FIG. 8D

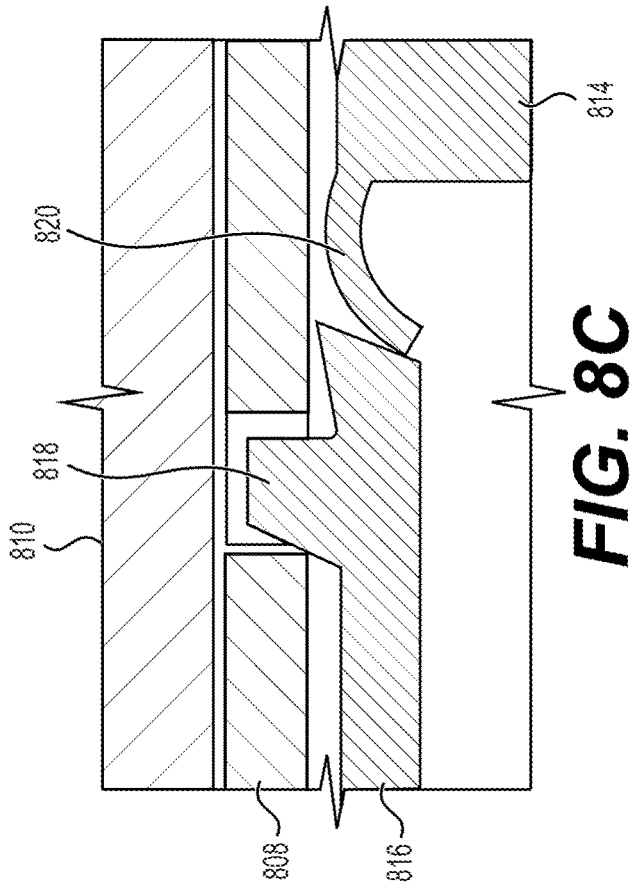

FIG. 8C

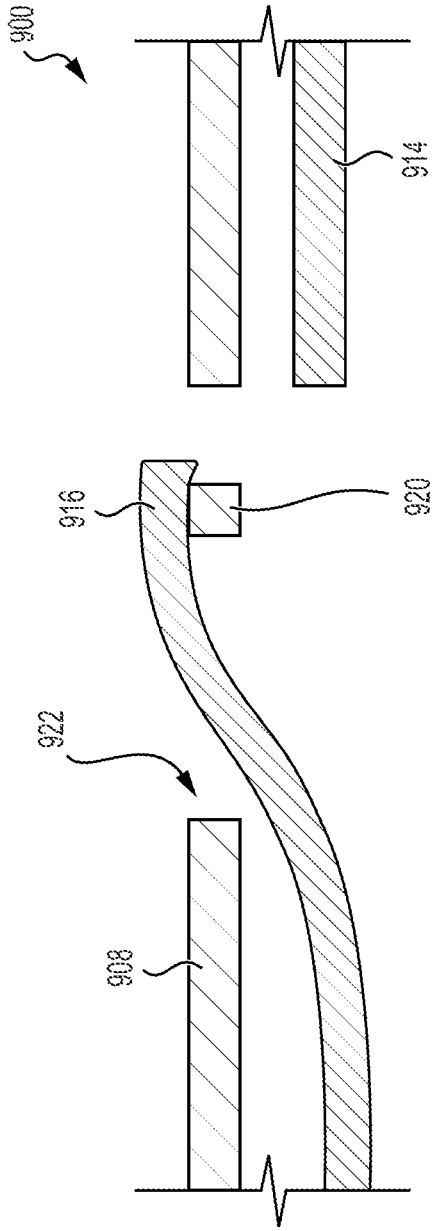

FIG. 9A

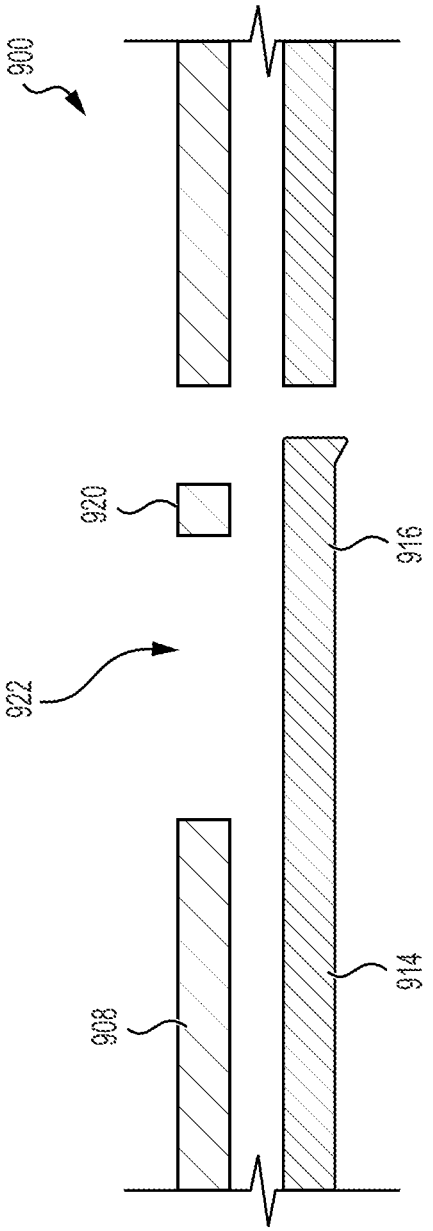

FIG. 9B

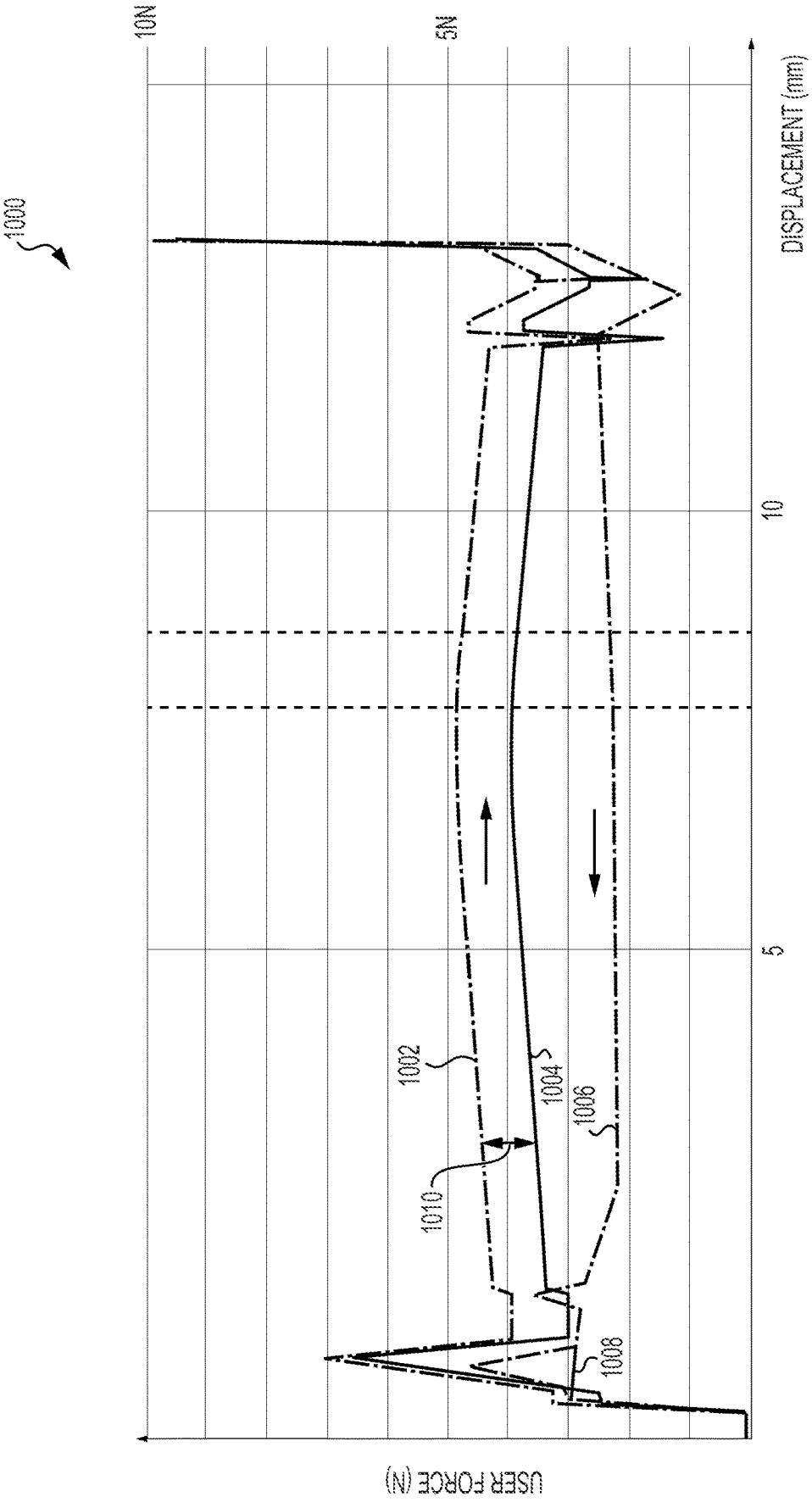
1000
10N
5N
DISPLACEMENT (mm)
10
5
1002
1004
1006
1008
1010
USER FORCE (N)

FIG. 10

INJECTOR DEVICE

TECHNICAL FIELD

This application relates to an injector device for delivery of a medicament, particularly to an auto-injector device.

BACKGROUND

Injector devices are used to deliver a range of medicaments. In an auto-injector device, some or all of the actions required to use the injector device in administering medicament to a user are automated.

It is known to provide an auto-injector device having a needle cover which is axially movable to cover and uncover a needle, with the needle cover being biased by a spring to extend over the needle. Typically, the user presses the needle cover against an injection site, against the force of the spring, to push the needle cover into the housing and to uncover the needle which is pushed into the injection site. Medicament is automatically dispensed from the needle via an automated mechanism. A user typically holds the needle cover in a holding position for a predetermined period of time, to ensure that the correct dose of medicament is dispensed from the device, before removing the device from the injection site.

Some users find it difficult to fully depress the needle cover due to the force required or the change in force experienced during the activation movement. This may result in the needle not entering the user's skin to the correct depth, pain, discomfort, a wet injection site, early device removal and/or partial delivery of the medicament.

SUMMARY

A first aspect of this disclosure provides a medicament delivery device for reducing a force required to activate the medicament delivery device, wherein the medicament delivery device comprises:

- a needle for injecting medicament into a user, the needle disposed at a distal end of the medicament delivery device;
- a needle cover and a body, wherein the needle cover is axially movable relative to the body between an initial position, in which the needle cover covers the needle, and an activated position for dispensing medicament from the medicament delivery device, wherein in the activated position the needle protrudes from the distal end of the needle cover; and
- a carrier configured to support a pre-filled syringe, wherein the carrier is disposed within the needle cover and comprises a deformable element configured to change from a first configuration in which the deformable element is engaged with the needle cover to a second configuration in which the deformable element is not engaged with the needle cover.

The deformable element may have the first configuration when the needle cover is in the initial position and may have the second configuration when the needle cover is in an intermediate position, between the initial position and the activated position.

Movement of the needle cover from the initial position to the intermediate position may cause the deformable element to be deformed from the first configuration to the second configuration.

The needle cover may comprise a cooperating element and wherein the deformable element may be configured to engage with the cooperating element in the first configuration and to be disengaged from the cooperating element in the second configuration. The cooperating element may comprise an aperture, a recess, a ridge or a frictional surface. The cooperating element may comprises a slot and the deformable element is configured to abut an edge of the slot in the first configuration.

Movement of the needle cover proximally from the initial position may cause the deformable element to disengage from the slot.

The deformable element may be configured to produce a sound when deforming from the first configuration to the second configuration. The deformable element may be configured to produce a vibration when deforming from the first configuration to the second configuration.

The deformable element may be configured to be deformed from a first shape in the first configuration to a second shape in the second configuration. The deformable element may be configured:

- to have a convex shape which protrudes from the carrier towards the needle cover in the first configuration; and
- to have a concave shape which curves away from the needle cover in the second configuration.

The deformable element may be in a stressed state when in the second configuration.

The deformable element may be configured to be permanently retained in the second configuration by a latching member.

The deformable element may be configured to break in the second configuration. The deformable element may comprise a flexible arm with a stress concentrating region and may be configured to break at the stress concentrating region when the flexible arm is deflected by the needle cover.

The deformable element may be in a stressed state when in the first configuration.

The medicament delivery device of the first aspect may comprise multiple deformable elements.

The needle cover may comprise multiple cooperating elements and each of the multiple deformable elements may be configured to engage with a respective one of the multiple cooperating elements in the first configuration and to be disengaged from the respective cooperating element in the second configuration.

There may be a zero normal force between the deformable element and the needle cover when the deformable element has the second configuration.

The deformable element may comprise a flexible arm and a protrusion disposed on a free end of the flexible arm. A distal facing edge of the protrusion may be bevelled.

The medicament delivery device may further comprise a spring configured to exert a spring force which biases the needle cover axially, towards the distal end of the medicament delivery device.

The medicament delivery device may further comprise the pre-filled syringe.

A second aspect of this disclosure provides a medicament delivery device for reducing a force required to activate the medicament delivery device, wherein the medicament delivery device comprises:

- a needle for injecting medicament into a user, the needle disposed at a distal end of the medicament delivery device;
- a needle cover and a body, wherein the needle cover is configured to be moved in a proximal direction into the body of the medicament delivery device to expose the needle;

a pre-filled syringe carrier, wherein the pre-filled syringe carrier is disposed within the needle cover and comprises a deformable element,

wherein the deformable element is configured:

prior to activation of the medicament delivery device, to have a first configuration in which the deformable element is engaged with the needle cover;

during an initial portion of an activation movement of the needle cover, to be forced to deform into a second configuration by movement of the needle cover, wherein the deformable element is not engaged with the needle cover when in the second configuration; and

to remain in the second configuration for the remainder of the activation movement of the needle cover so as to reduce a force required to move the needle cover in a proximal direction into the body of the medicament delivery device.

The deformable element may deform permanently into the second configuration.

The deformable element may be configured to be deformed from a first shape in the first configuration to a second shape in the second configuration.

The deformable element may be configured: to have a convex shape which protrudes from the carrier towards the needle cover in the first configuration; an to have a concave shape which curves away from the needle cover in the second configuration.

The deformable element may be configured to be permanently retained in the second configuration by a latching member.

The deformable element may be in a stressed state when in the first configuration.

The deformable element may be configured to break in the second configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the accompanying drawings in which:

FIG. **1**A shows an injector device with a cap attached;

FIG. **1**B shows the injector device of FIG. **1**A with the cap removed;

FIG. **2**A shows a simplified view of an injector device prior to use;

FIG. **2**B shows a view of the device of FIG. **2**A with injector device in the holding position;

FIG. **3**A shows a device in a pre-use state;

FIG. **3**B shows the device at the start of an activation movement;

FIG. **3**C shows the device in a mid-activation state;

FIG. **3**D shows the device in an activated state;

FIG. **4**A is a perspective view of a cross section of the device in the initial state of FIG. **3**A;

FIG. **4**B is a perspective view of a cross section of the device in the mid-activation state of FIG. **3**C;

FIG. **5**A shows a medicament delivery device according to a first embodiment in an initial state;

FIG. **5**B shows the medicament delivery device of the first embodiment at the start of an activation movement;

FIG. **5**C shows the medicament delivery device of the first embodiment in an activated state;

FIG. **6**A is a perspective view of a cross section of the medicament delivery device of the first embodiment in the initial state of FIG. **5**A;

FIG. **6**B is a perspective view of a cross section of the medicament delivery device of the first embodiment at the start of an activation movement (equivalent to FIG. **5**B);

FIG. **7**A shows a medicament delivery device according to a second embodiment in an initial state;

FIG. **7**B shows the medicament delivery device of the second embodiment at the start of an activation movement;

FIG. **7**C shows the medicament delivery device of the second embodiment in an activated state;

FIG. **8**A shows a medicament delivery device according to a third embodiment in an initial state;

FIG. **8**B shows the medicament delivery device of the second embodiment in an activated state;

FIG. **8**C shows a close-up of a deformable element of the third embodiment in a first configuration;

FIG. **8**D shows a close-up of a deformable element of the third embodiment in a second configuration;

FIG. **9**A shows portions of a medicament delivery device according to a fourth embodiment with a deformable element in a first configuration;

FIG. **9**B shows portions of a medicament delivery device according to a fourth embodiment with a deformable element in a second configuration; and

FIG. **10** is a force profile graph illustrating the force profile of a first device and the medicament delivery devices according to the first to fourth embodiments.

DETAILED DESCRIPTION

A drug delivery device, as described herein, may be configured to inject a medicament into a patient. For example, delivery could be sub-cutaneous, intra-muscular, or intravenous. Such a device could be operated by a patient or care-giver, such as a nurse or physician, and can include various types of safety syringe, pen-injector, or auto-injector. The device can include a cartridge-based system that requires piercing a sealed ampule before use. Volumes of medicament delivered with these various devices can range from about 0.5 ml to about 2 ml. Yet another device can include a large volume device ("LVD") or patch pump, configured to adhere to a patient's skin for a period of time (e.g., about 5, 15, 30, 60, or 120 minutes) to deliver a "large" volume of medicament (typically about 2 ml to about 10 ml).

In combination with a specific medicament, the presently described devices may also be customized in order to operate within required specifications. For example, the device may be customized to inject a medicament within a certain time period (e.g., about 3 to about 20 seconds for auto-injectors, and about 10 minutes to about 60 minutes for an LVD). Other specifications can include a low or minimal level of discomfort, or to certain conditions related to human factors, shelf-life, expiry, biocompatibility, environmental considerations, etc. Such variations can arise due to various factors, such as, for example, a drug ranging in viscosity from about 3 cP to about 50 cP. Consequently, a drug delivery device will often include a hollow needle ranging from about 25 to about 31 Gauge in size. Common sizes are 27 and 29 Gauge.

The delivery devices described herein can also include one or more automated functions. For example, one or more of needle insertion, medicament injection, and needle retraction can be automated. Energy for one or more automation steps can be provided by one or more energy sources. Energy sources can include, for example, mechanical, pneumatic, chemical, or electrical energy. For example, mechanical energy sources can include springs, levers, elastomers, or other mechanical mechanisms to store or release energy. One or more energy sources can be combined into a single device. Devices can further include gears, valves, or other

mechanisms to convert energy into movement of one or more components of a device.

The one or more automated functions of an auto-injector may each be activated via an activation mechanism. Such an activation mechanism can include one or more of a button, a lever, a needle sleeve, or other activation component. Activation of an automated function may be a one-step or multi-step process. That is, a user may need to activate one or more activation components in order to cause the automated function. For example, in a one-step process, a user may depress a needle sleeve against their body in order to cause injection of a medicament. Other devices may require a multi-step activation of an automated function. For example, a user may be required to depress a button and retract a needle shield in order to cause injection.

In addition, activation of one automated function may activate one or more subsequent automated functions, thereby forming an activation sequence. For example, activation of a first automated function may activate at least two of needle insertion, medicament injection, and needle retraction. Some devices may also require a specific sequence of steps to cause the one or more automated functions to occur. Other devices may operate with a sequence of independent steps.

Some delivery devices can include one or more functions of a safety syringe, pen-injector, or auto-injector. For example, a delivery device could include a mechanical energy source configured to automatically inject a medicament (as typically found in an auto-injector) and a dose setting mechanism (as typically found in a pen-injector).

According to some embodiments of the present disclosure, an exemplary drug delivery device **10** is shown in FIGS. **1**A & **1**B. Device **10**, as described above, is configured to inject a medicament into a patient's body. Device **10** includes a housing **11** which typically contains a reservoir containing the medicament to be injected (e.g., a syringe) and the components required to facilitate one or more steps of the delivery process. Device **10** can also include a cap assembly **12** that can be detachably mounted to the housing **11**. Typically a user removes cap **12** from housing **11** before device **10** can be operated.

As shown, housing **11** is substantially cylindrical and has a substantially constant diameter along the longitudinal axis X. The housing **11** has a distal region **20** and a proximal region **21**. The term "distal" refers to a location that is relatively closer to a site of injection, and the term "proximal" refers to a location that is relatively further away from the injection site.

Device **10** can also include a needle sleeve **13** coupled to housing **11** to permit movement of sleeve **13** relative to housing **11**. For example, sleeve **13** can move in a longitudinal direction parallel to longitudinal axis X. Specifically, movement of sleeve **13** in a proximal direction can permit a needle **17** to extend from distal region **20** of housing **11**.

Insertion of needle **17** can occur via several mechanisms. For example, needle **17** may be fixedly located relative to housing **11** and initially be located within an extended needle sleeve **13**. Proximal movement of sleeve **13** by placing a distal end of sleeve **13** against a patient's body and moving housing **11** in a distal direction will uncover the distal end of needle **17**. Such relative movement allows the distal end of needle **17** to extend into the patient's body. Such insertion is termed "manual" insertion as needle **17** is manually inserted via the patient's manual movement of housing **11** relative to sleeve **13**.

Another form of insertion is "automated," whereby needle **17** moves relative to housing **11**. Such insertion can be triggered by movement of sleeve **13** or by another form of activation, such as, for example, a button **22**. As shown in FIGS. **1**A & **1**B, button **22** is located at a proximal end of housing **11**. However, in other embodiments, button **22** could be located on a side of housing **11**.

Other manual or automated features can include drug injection or needle retraction, or both. Injection is the process by which a bung or piston **23** is moved from a proximal location within a syringe to a more distal location within the syringe in order to force a medicament from the syringe through needle **17**. In some embodiments, a drive spring is under compression before device **10** is activated. A proximal end of the drive spring can be fixed within proximal region **21** of housing **11**, and a distal end of the drive spring can be configured to apply a compressive force to a proximal surface of piston **23**. Following activation, at least part of the energy stored in the drive spring can be applied to the proximal surface of piston **23**. This compressive force can act on piston **23** to move it in a distal direction. Such distal movement acts to compress the liquid medicament within the syringe, forcing it out of needle **17**.

Following injection, needle **17** can be retracted within sleeve **13** or housing **11**. Retraction can occur when sleeve **13** moves distally as a user removes device **10** from a patient's body. This can occur as needle **17** remains fixedly located relative to housing **11**. Once a distal end of sleeve **13** has moved past a distal end of needle **17**, and needle **17** is covered, sleeve **13** can be locked. Such locking can include locking any proximal movement of sleeve **13** relative to housing **11**.

Another form of needle retraction can occur if needle **17** is moved relative to housing **11**. Such movement can occur if the syringe within housing **11** is moved in a proximal direction relative to housing **11**. This proximal movement can be achieved by using a retraction spring, located in distal region **20**. A compressed retraction spring, when activated, can supply sufficient force to the syringe to move it in a proximal direction. Following sufficient retraction, any relative movement between needle **17** and housing **11** can be locked with a locking mechanism. In addition, button **22** or other components of device **10** can be locked as required.

FIGS. **2**A and **2**B show a simplified view of a device **110** having a needle cover **113** which is axially movable to cover and uncover the needle **117**. The needle cover **113** is biased by a spring **104** to extend over the needle **117**.

FIG. **2**A shows the device before use, in which the needle cover **113** is exposed out of the end of the device body **103** and covers the needle **117**. A force can be applied by a user against a spring force **125** to move the needle cover **113** from the position shown in FIG. **2**A towards a holding position shown in FIG. **2**B, and a holding force **120** can be applied to maintain the needle cover in the holding position.

Typically the user presses the needle cover **113** against an injection site **115** to push the needle cover **113** at least partially into the device body **103**. The exposed needle **117** is pushed into the injection site **115**. In the holding position, medicament is automatically dispensed from the needle **117** via an automated mechanism. A user typically holds the needle cover **113** in the holding position for a predetermined period of time, to ensure that the correct dose of medicament is dispensed from the device **110**, before removing the device from the injection site **115**.

The spring force **125** against which the user must applies a force to move the needle cover **113** is one component of the "activation force" of the device **110**. The activation force refers to the force or force profile that the user exerts on the device **110** to move the needle cover **113** from the position

shown in FIG. **2**A to the position shown in FIG. **2**B. If this force or force profile is not well balanced, it can lead to difficulty in activating the device **100** for some users, or increase the pain or anxiety associated with using the device.

FIGS. **3**A to **3**D show further details of the operation of the device **110**. These Figures each show a cross section of the one half of the device **110** during various stages of activation of the device.

FIG. **3**A shows the device in a pre-use state, may also be called an initial state or initial position. The needle cover **113** covers the needle **117** in this position. A spring may bias the needle cover **113** distally so that it extends over the needle **117**. The device **110** also comprises a carrier **300**, which supports a pre-filled syringe **302**. The needle **117** is in fluid communication with the pre-filled syringe **302** and extends from the distal end of the pre-filled syringe **302**. The carrier **300** comprises a resilient member **304** which takes the form of a flexible arm which extends axially (or longitudinally) and which has a protrusion **306** on the free end of the flexible arm. The protrusion **306** extends radially from the flexible arm to engage with a first slot in the needle cover **113**.

Although one resilient member **304** is shown in FIG. **3**A, the carrier **300** may comprise two or more resilient members **304**. For example, two resilient members **304** may be disposed opposite each other on the carrier **300** and may engage with corresponding slots in the needle cover **113**. Having the resilient member **304** engage a slot in the needle cover **113** in this initial position may prevent axial travel of the needle cover **113** during assembly of the device **110** and may help to prevent inadvertent activation of the device **110**.

FIG. **3**B shows the device **110** at the start of an activation movement. A distal force is applied via the body **103** while the needle cover **113** is placed against the user's skin, causing the needle cover **113** to move proximally into the device **110**. During this initial movement, the resilient member **304** is deflected and exits the first slot in the needle cover **113**. The resilient member **304** abuts an inner surface of the needle cover **113** resulting in a normal force between these components. This leads to a frictional force which resists proximal movement of the needle cover **113** into the device **110** and therefore increases the force required to activate the device **110**.

FIG. **3**C shows the device **110** in a mid-activation state. In this position, the needle **117** has protruded from the end of the needle cover **113**, but the medicament dispensing mechanism of the device **110** has not yet been triggered. As can be seen, the resilient member **304** is still in a deflected state and still exerts and normal and frictional force on the needle cover **113**.

FIG. **3**D shows the device **110** in an activated state. In this position the needle cover **113** is fully displaced into the device **110**, the needle **117** protrudes from the end of the needle cover **113** to its maximum extend and the medicament dispensing mechanism of the device **110** is triggered. As can be seen, the resilient member **304** is still in a deflected state and still exerts and normal and frictional force on the needle cover **113**.

After the medicament has been delivered, during removal of the device **110**, the sequence of FIGS. **3**A to **3**D is reversed. The resilient member **304** remains in a deflected state until the needle cover **113** returns to the initial position.

FIG. **4**A is a perspective view of a cross section of the device **110** in the initial state (as also shown in FIG. **3**A). In this view it can be seen that the protrusion **306** of the resilient member **304** abuts an end face of the slot **400** in the needle cover **113**. The carrier **300** comprises two resilient members **304** on opposite sides and there are two corresponding slots **400** in the needle cover **113**.

FIG. **4**B is a perspective view of a cross section of the device **110** in a mid-activation state (as also shown in FIG. **3**C). In this view it can be seen that the resilient members **304** are deflected, so that the protrusions **306** on the free ends of the flexible arms contact the inner surface of the needle cover **113**, increasing the force needed to move the needle cover **113** proximally with respect to the body **103** of the device **110**.

FIGS. **5**A to **5**C shows features of a first embodiment of a medicament delivery device **500**, which is also referred to herein as an injector device. These Figures each show a cross section of the one half of the device **500** during various stages of activation of the device.

The device has a distal end **502** and a proximal end **504**. The device **500** has a needle **506** for injecting medicament into a user at an injection site, a needle cover **508** and a body **510**. The body **510** is configured to be gripped by a user. The body **510** forms part of the external surface of the device. The device **500** houses a pre-filled syringe **512**. The needle **506** is in fluid communication with the pre-filled syringe **512** and extends from the distal end of the pre-filled syringe **512**. The needle cover **508** is axially movable relative to the body **510** between an initial position, shown in FIG. **5**A, in which the needle cover **508** covers the needle **506**, and an activated position, shown in FIG. **5**C, for dispensing medicament from the device. In the activated position, the needle **506** protrudes from the distal end of the needle cover **508**.

A spring may exert a spring force against the needle cover **508** which biases the needle cover axially, in the distal direction. A force can be applied by a user against the force of the spring to move the needle cover **508** from the position shown in FIG. **5**A towards the position shown in FIG. **5**C.

Medicament is dispensed from the medicament delivery device **500** via the needle **506** while the needle cover **508** is in the activated position. An automated mechanism is triggered to start the dispensing of medicament when the needle cover **508** reaches a predetermined axial position within the housing. The predetermined position is located just distally of the activated position. The automated mechanism may comprise a plunger which is automatically released when the needle cover **508** reaches the predetermined axial position. When the plunger is released it moves within the pre-filled syringe to dispense medicament from the syringe through the needle **506**.

Typically the user removes a cap from the distal end of the medicament delivery device **500**. The user presses the needle cover **508** against an injection site to move the needle cover **508** axially relative to the body **510** and to uncover the needle **506**. The needle **506** is pushed into the injection site. The automated mechanism is released, and medicament is automatically dispensed from the device via the needle **506**. The user holds the needle cover **508** in the activated position while the medicament is dispensed.

FIG. **5**A shows the device **500** in a pre-use state, which may also be called an initial state or initial position. The needle cover **508** covers the needle **506** in this position. The device **500** also comprises a carrier **514**, which supports the pre-filled syringe **512**. The carrier **514** comprises a deformable element **516** which takes the form of a flexible component. FIG. **5**A shows the deformable element **516** in a first configuration in which it has a convex shape which protrudes from the carrier **514** towards the needle cover **208**. The deformable element **516** comprises a protrusion **518** disposed on the flexible member. The protrusion **518** may be positioned approximately in the centre of the flexible mem-

ber and directed towards the carrier **514**. The flexible member may be an extruded piece of the body of the carrier or a separate element, secured at both ends to the body of the carrier **514**.

The deformable element **516** may be stressed when in the first configuration. For example, some compression or tension forces may be present in the flexible member. Alternatively, the deformable element **516** may be in a relaxed state in the first configuration.

The needle cover has a cooperating element, which may take the form of an aperture, a recess, a ridge or a frictional surface. The deformable element **516** is configured to engage with the cooperating element while in the first configuration and thereby to provide a resistance to proximal movement of the needle cover **508** relative to the carrier **514** and body **510**. In this embodiment, the cooperating element has the form of a slot (see FIGS. **6**A and **6**B) and the deformable element is configured to abut an edge of the slot in the first configuration. The protrusion **518** of the deformable element **516** may abut a proximally facing edge of the slot. A distal facing edge of the protrusion **518** may be beveled, to allow the protrusion **518** to be forced radially inwards when the needle covers is pushed proximally.

Although one deformable element **516** is shown in FIG. **5**A, the carrier **514** may comprise two or more deformable elements **516**. For example, two deformable elements **516** may be disposed opposite each other on the carrier **514** and may engage with corresponding slots in the needle cover **508**.

FIG. **5**B shows the device **500** at the start of an activation movement. A distal force is applied via the body **510** while the needle cover **508** is placed against the user's skin, causing the needle cover **508** to move proximally into the device **500**. In this position, the needle cover **508** is in an intermediate position, between the initial position and the activated position.

During this initial movement, the deformable element **516** is deflected and exits the slot in the needle cover **508**. In particular a normal force is exerted on the protrusion **518** which is forced radially inwards. This causes the flexible member to bend downwards or to become less convex. As the main body of the carrier **514** is rigid, compression forces build in the deformable element **516**. When the deformable element **516** has deflected past a critical position, e.g. beyond a position parallel with the fixed end points of the flexible member, then it snaps into a second configuration, as shown in FIG. **5**B. In this manner, movement of the needle cover **508** from the initial position to the intermediate position causes the deformable element **516** to be deformed from the first configuration to the second configuration. In the second configuration, the deformable element **516** has a concave shape which curves away from the needle cover **508**. Thus the deformable element **516** deforms from a first shape in the first configuration to a second shape in the second configuration.

The carrier **514** may have an aperture or recess underneath the deformable element **516** to allow room for it to deform into the concave shape. The deformable element **516** may be stressed when in the second configuration. For example, some compression or tension forces may be present in the flexible member. Alternatively, the deformable element **516** may be in a relaxed state in the second configuration.

The deformable element **516** may produce a sound when deforming from the first configuration to the second configuration, for example a snapping sound. This may be used to provide feedback to a user or to a sensor within the device **500** or attached to the device **500**. The snap sound may be produced by the deformable element **516** itself, or by the deformable element **516** striking an inner surface of a recess in the carrier **514** as it transitions to the second shape.

Alternatively, or in addition, the deformable element **516** may be configured to produce a vibration when deforming from the first configuration to the second configuration. Again, this may be used to provide feedback to a user or to a sensor within the device **500** or attached to the device **500**. The vibration may be produced by the deformable element **516** itself, or by the deformable element **516** striking an inner surface of a recess in the carrier **514** as it transitions to the second shape.

The deformable element **516** may be referred to as a permanently deformable element or irreversibly deformable element, since in some examples after the element is deformed, the deformation cannot be reversed. In this embodiment, the deformable element **516** does not again assume a convex shape.

FIG. **5**C shows the device **500** in an activated state. In this position the needle cover **508** is fully displaced into the device **500** and is in an activated position. The needle **506** protrudes from the end of the needle cover **508** to its maximum extend and the medicament dispensing mechanism of the device **500** is triggered. As can be seen, the deformable element **516** remains in the second configuration. Thus the deformable element **516** does not exert any normal or friction force on the needle cover **508** in this position or at any point after the intermediate position. The activation force on the needle cover **508** required after the intermediate position is reached is therefore reduced compared to other devices.

After the medicament has been delivered, during removal of the device **500**, the movement of the needle cover **508** is reversed, but the deformable element **516** remains in its second configuration.

FIG. **6**A is a perspective view of a cross section of the device **500** in the initial state (as also shown in FIG. **5**A). In this Figure, the needle cover **508** is in the initial position. It can be seen that the deformable element **516** has a convex shape and a protrusion **518** of the deformable element **516** abuts a proximally facing end face of a slot **600** in the needle cover **508**. The slot **600** extends axially and is an aperture through the wall of the needle cover **508**. In some other embodiments, the slot **600** may be provided as a recess in the inner surface of the needle cover **508**, which does not extend completely through the wall of the needle cover **508**, but which is deep enough to accommodate the protrusion **518** of the deformable element **516** in the first configuration.

FIG. **6**B is a perspective view of a cross section of the device **500** at the start of an activation movement (as also shown in FIG. **5**B). In this position, the needle cover **508** has moved proximally to an intermediate position and the needle **506** is still shielded by the needle cover **508**. The medicament dispensing mechanism of the device **500** has not yet been triggered.

In this intermediate position, the deformable element **516** has a convex shape and is in a second configuration. The deformable element **516** remains in this second configuration for the remainder of the activation movement and throughout device removal. No part of the deformable element **516** is in contact with the needle cover **508** and thus the deformable element **516** does not exert any normal or friction force on the needle cover **508** in this position.

In the embodiment depicted, the carrier **514** comprises two deformable elements **516** on opposite sides and there are two corresponding slots **600** in the needle cover **508**. In

general, a symmetrical arrangement of deformable elements **516** may help to ensure a consistent force profile when the device **500** is used.

FIGS. **7**A to **7**C shows features of a second embodiment of a medicament delivery device **700**, which is also referred to herein as an injector device. These Figures each show a cross section of the one half of the device **700** during various stages of activation of the device.

The device has a distal end **702** and a proximal end **704**. The device **700** has a needle **706** for injecting medicament into a user at an injection site, a needle cover **708** and a body **710**. The body **710** is configured to be gripped by a user. The body **710** forms part of the external surface of the device. The device **700** houses a pre-filled syringe **712**. The needle **706** is in fluid communication with the pre-filled syringe **712** and extends from the distal end of the pre-filled syringe **712**. The needle cover **708** is axially movable relative to the body **710** between an initial position, shown in FIG. **7**A, in which the needle cover **708** covers the needle **706**, and an activated position, shown in FIG. **7**C, for dispensing medicament from the device. In the activated position, the needle **706** protrudes from the distal end of the needle cover **708**.

A spring may exert a spring force against the needle cover **708** which biases the needle cover axially, in the distal direction. A force can be applied by a user against the force of the spring to move the needle cover **708** from the position shown in FIG. **7**A towards the position shown in FIG. **7**C.

Medicament is dispensed from the medicament delivery device **700** via the needle **706** while the needle cover **708** is in the activated position. An automated mechanism is triggered to start the dispensing of medicament when the needle cover **708** reaches a predetermined axial position within the housing. The predetermined position is located just distally of the activated position. The automated mechanism may comprise a plunger which is automatically released when the needle cover **708** reaches the predetermined axial position. When the plunger is released it moves within the pre-filled syringe to dispense medicament from the syringe through the needle **706**.

Typically the user removes a cap from the distal end of the medicament delivery device **700**. The user presses the needle cover **708** against an injection site to move the needle cover **708** axially relative to the body **710** and to uncover the needle **706**. The needle **706** is pushed into the injection site. The automated mechanism is released, and medicament is automatically dispensed from the device via the needle **706**. The user holds the needle cover **708** in the activated position while the medicament is dispensed.

FIG. **7**A shows the device **700** in a pre-use state, which may also be called an initial state or initial position. The needle cover **708** covers the needle **706** in this position. The device **700** also comprises a carrier **714**, which supports the pre-filled syringe **712**. The carrier **714** comprises a deformable element **716** which takes the form of a flexible arm. The flexible arm may be an extruded piece of the body of the carrier or a separate element, secured at one end to the body of the carrier **714**. The free end of the arm comprises a protrusion **718** directed towards the carrier **714**.

FIG. **7**A shows the deformable element **716** in a first configuration in which it is engaged with a cooperating element of the needle cover **708**. The cooperating element may take the form of an aperture, a recess, a ridge or a frictional surface. The deformable element **716** is configured to engage with the cooperating element while in the first configuration and thereby to provide a resistance to proximal movement of the needle cover **708** relative to the carrier **714** and body **710**. In this embodiment, the cooperating element has the form of a slot and the deformable element is configured to abut an edge of the slot in the first configuration. The protrusion **718** of the deformable element **716** may abut a proximally facing edge of the slot. A distal facing edge of the protrusion **718** may be beveled, to allow the protrusion **718** to be forced radially inwards when the needle covers is pushed proximally.

The deformable element **716** has a stress concentrating region **720**. The stress concentrating region **720** may be located approximately half-way between the fixed and free ends of the flexible arm. The stress concentrating region **720** may comprise a thinned or weakened area of the flexible arm. The deformable element **716** may be in a relaxed state in the first configuration.

Although one deformable element **716** is shown in FIG. **7**A, the carrier **714** may comprise two or more deformable elements **716**. For example, two deformable elements **716** may be disposed opposite each other on the carrier **714** and may engage with corresponding slots in the needle cover **708**.

FIG. **7**B shows the device **700** at the start of an activation movement. A distal force is applied via the body **710** while the needle cover **708** is placed against the user's skin, causing the needle cover **708** to move proximally into the device **700**. In this position, the needle cover **708** is in between the initial position and the activated position.

During this initial movement, the deformable element **716** is deflected and exits the slot in the needle cover **708**. In particular a normal force is exerted on the protrusion **718** which is forced radially inwards. This causes the flexible arm to bend downwards and be put under stress.

When the deformable element **716** is deflected past a critical position, e.g. coinciding with the amount of deflection produced by exiting the slot in the needle cover **708**, the stress in the stress concentrating region causes the deformable element **716** to break, as shown in FIG. **7**C. In this manner, movement of the needle cover **708** from the initial position to an intermediate position causes the deformable element **716** to be deformed from the first configuration to the second configuration. In the second configuration, the deformable element **716** has broken. FIG. **7**C shows the device **700** in an activated state. However, the deformable element **716** may be configured to break before the needle cover **708** reaches the activated position. For example, the deformable element **716** may break as soon as, or shortly after, the protrusion **718** of the flexible arm exits the slot in the needle cover **708**.

The deformable element **716** may be configured to break entirely into two pieces. The carrier **714** may have an aperture or recess underneath the deformable element **716** to allow room for the broken end piece of the deformable element **716** to be accommodated.

The deformable element **716** may produce a sound when deforming from the first configuration to the second configuration, for example a snapping sound. This may be used to provide feedback to a user or to a sensor within the device **700** or attached to the device **700**. The snap sound may be produced by the deformable element **716** itself when it breaks.

Alternatively, or in addition, the deformable element **716** may be configured to produce a vibration when deforming from the first configuration to the second configuration. Again, this may be used to provide feedback to a user or to a sensor within the device **700** or attached to the device **700**. The vibration may be produced by the deformable element **716** itself when breaking.

The deformable element **716** may be referred to as a permanently deformable element or irreversibly deformable element, since after the element is deformed, the deformation cannot be reversed. In this embodiment, after it is broken, the deformable element **716** does not exert a force on the needle cover for the remainder of its movement or during device removal. The activation force on the needle cover **708** required after the intermediate position is reached is therefore reduced compared to prior art devices.

After the medicament has been delivered, during removal of the device **700**, the movement of the needle cover **708** is reversed, but the deformable element **716** remains in its second configuration.

FIGS. **8**A to **8**D shows features of a third embodiment of a medicament delivery device **800**, which is also referred to herein as an injector device. These Figures each show a cross section of the device **800** or a part of the device **800** during various stages of activation of the device.

The device has a distal end **802** and a proximal end **804**. The device **800** has a needle **806** for injecting medicament into a user at an injection site, a needle cover **808** and a body **810**. The body **810** is configured to be gripped by a user. The body **810** forms part of the external surface of the device. The device **800** houses a pre-filled syringe **812**. The needle **806** is in fluid communication with the pre-filled syringe **812** and extends from the distal end of the pre-filled syringe **812**. The needle cover **808** is axially movable relative to the body **810** between an initial position, shown in FIG. **8**A, in which the needle cover **808** covers the needle **806**, and an activated position, shown in FIG. **8**C, for dispensing medicament from the device. In the activated position, the needle **806** protrudes from the distal end of the needle cover **808**.

A spring may exert a spring force against the needle cover **808** which biases the needle cover axially, in the distal direction. A force can be applied by a user against the force of the spring to move the needle cover **808** from the position shown in FIG. **8**A towards the position shown in FIG. **8**B.

Medicament is dispensed from the medicament delivery device **800** via the needle **806** while the needle cover **808** is in the activated position. An automated mechanism is triggered to start the dispensing of medicament when the needle cover **808** reaches a predetermined axial position within the housing. The predetermined position is located just distally of the activated position. The automated mechanism may comprise a plunger which is automatically released when the needle cover **808** reaches the predetermined axial position. When the plunger is released it moves within the pre-filled syringe to dispense medicament from the syringe through the needle **806**.

Typically the user removes a cap from the distal end of the medicament delivery device **800**. The user presses the needle cover **808** against an injection site to move the needle cover **808** axially relative to the body **810** and to uncover the needle **806**. The needle **806** is pushed into the injection site. The automated mechanism is released, and medicament is automatically dispensed from the device via the needle **806**. The user holds the needle cover **808** in the activated position while the medicament is dispensed.

FIG. **8**A shows the device **800** in a pre-use state, which may also be called an initial state or initial position. The needle cover **808** covers the needle **806** in this position. The device **800** also comprises a carrier **814**, which supports the pre-filled syringe **812**. The carrier **814** comprises a deformable element **816** which takes the form of a flexible arm. The flexible arm may be an extruded piece of the body of the carrier or a separate element, secured at one end to the body of the carrier **814**. The free end of the arm comprises a protrusion **818** directed towards the carrier **814**.

FIG. **8**A shows the deformable element **816** in a first configuration in which it is engaged with a cooperating element of the needle cover **808**. The cooperating element may take the form of an aperture, a recess, a ridge or a frictional surface. The deformable element **816** is configured to engage with the cooperating element while in the first configuration and thereby to provide a resistance to proximal movement of the needle cover **808** relative to the carrier **814** and body **810**. In this embodiment, the cooperating element has the form of a slot and the deformable element is configured to abut an edge of the slot in the first configuration. The protrusion **818** of the deformable element **816** may abut a proximally facing edge of the slot. A distal facing edge of the protrusion **818** may be beveled, to allow the protrusion **818** to be forced radially inwards when the needle covers is pushed proximally.

The carrier **814** also comprises a latching member **820**. The latching member **820** may comprise a flexible projection which extends distally form a portion of the carrier **814** and has a free end which contacts an underside or beveled end face of the deformable element **816**, which may hold it in the first configuration.

Although one deformable element **816** is shown in FIG. **8**A, the carrier **814** may comprise two or more deformable elements **816**. For example, two deformable elements **816** may be disposed opposite each other on the carrier **814** and may engage with corresponding slots in the needle cover **808**.

FIG. **8**C shows a close-up of the free end of the deformable element **816** and the latching member **820** in the first configuration.

FIG. **8**B shows the device **800** in an activated position. A distal force is applied via the body **810** while the needle cover **808** is placed against the user's skin, causing the needle cover **808** to move proximally into the device **800**. The needle cover **808** thus enters a position between the initial position and the activated position. During this initial movement, the deformable element **816** is deflected and exits the slot in the needle cover **808**. In particular a normal force is exerted on the protrusion **818** which is forced radially inwards. This causes the flexible arm to bend downwards and to overcome the resisting force of the latching member **820**. The latching member **820** may bend downwards under the force exerted by the deformable element **816** until the free end of the latching member **820** clears the free end of the deformable element **816**. At this point the latching member **820** snaps back up and abuts a top side of the deformable element **816**. In this manner, movement of the needle cover **808** from the initial position to an intermediate position causes the deformable element **816** to be deformed from the first configuration to the second configuration.

FIG. **8**B shows the device **800** in an activated state. However, the latching member **820** may be configured to clear the free end of the deformable element **816** before the needle cover **808** reaches the activated position. For example, latching member **820** may clear the free end of the deformable element **816** as soon as, or shortly after, the protrusion **818** of the flexible arm exits the slot in the needle cover **808**.

The deformable element **816** may be in a relaxed state in the first configuration and a stressed state in the second configuration. The latching member **820** may be biased downwards (towards the center axis of the device **800**). It may therefore exert a force on the top side of the deformable

element **816** to maintain it in the second configuration. Alternatively, the deformable element **816** may be biased towards the second configuration. Thus, in the first configuration, the deformable element **816** is held in a stressed state by the latching member **820**. The latching member **820** may still exert some downward biasing force on the top side of the deformable element **816** in the second configuration to ensure that no element contacts the needle cover **808** for the remainder of the activation movement.

The carrier **814** may have an aperture or recess underneath the deformable element **816** to allow room for it to deform into the second configuration.

The deformable element **816** and/or the latching member **820** may produce a sound when the deformable element **816** deforms from the first configuration to the second configuration, for example a snapping sound. This may be used to provide feedback to a user or to a sensor within the device **800** or attached to the device **800**. The snap sound may be produced by the free end of the latching member **820** striking the protrusion **818** of the deformable element **816** or some other part of the free end of the deformable element **816**.

Alternatively, or in addition, the deformable element **816** may be configured to produce a vibration when deforming from the first configuration to the second configuration. Again, this may be used to provide feedback to a user or to a sensor within the device **800** or attached to the device **800**. The vibration may be produced by the free end of the latching member **820** striking the protrusion **818** of the deformable element **816** or some other part of the free end of the deformable element **816**.

The deformable element **816** may be referred to as a permanently deformable element or irreversibly deformable element, since after the element is deformed, the deformation cannot be reversed. The deformable element **816** is either biased towards the second configuration or is restrained in the second configuration by the latching member **820**, or both. The activation force on the needle cover **808** required after the intermediate position is reached is therefore reduced compared to other devices.

FIG. **8**D shows a close-up of the free end of the deformable element **816** and the latching member **820** in the second configuration.

After the medicament has been delivered, during removal of the device **800**, the movement of the needle cover **808** is reversed, but the deformable element **816** remains in its second configuration.

FIGS. **9**A and **9**B shows features of a fourth embodiment of a medicament delivery device **900**, which is also referred to herein as an injector device. These Figures each show a cross section of a portion of a needle cover **908** and a carrier **914**.

FIG. **9**A shows a close up of a portion of the carrier **914** with a deformable element **916** and the region of the needle cover **908** with which it interacts. The other parts of the medicament delivery device **900** may be the same as those shown and described in the preceding embodiments.

FIG. **9**A shows the device **900** in a pre-use state, which may also be called an initial state or initial position. The needle cover **908** covers the needle in this position. The deformable element **916** takes the form of a flexible arm. The flexible arm may be an extruded piece of the body of the carrier or a separate element, secured at one end to the body of the carrier **914**. The free end of the arm may comprise a shaped portion which may be slightly larger in cross section than the reminder of the flexible arm.

The needle cover **908** has at least one slot **922** and a ledge feature **920** located within the slot **922** or at one end of the slot. FIG. **9**A shows the deformable element **916** in a first configuration in which it is engaged with the ledge feature **920** of the needle cover **908**. In particular, the deformable element **916** is in a flexed or stressed state and abuts an outward facing surface of the ledge feature **920**. A part of the deformable element **916** therefore protrudes through the slot **922** and beyond an external circumference of the needle cover **908**. A recess may be provided in the body of the medicament delivery device **900** to allow space for the free end of the deformable element **916** in the first configuration. The body may also be shaped so as to have a larger diameter at this point.

The deformable element **916** is placed into the flexed first configuration during manufacture of the medicament delivery device **900** and remains in this state until the device is activated.

Although one deformable element **916** is shown in FIG. **9**A, the carrier **914** may comprise two or more deformable elements **916**. For example, two deformable elements **916** may be disposed opposite each other on the carrier **914** and may engage with corresponding ledge features **920** in the needle cover **908**.

FIG. **9**B shows the device **900** with the deformable element **916** in a second configuration. During activation of the device **900**, a distal force is applied via the body while the needle cover **908** is placed against the user's skin, causing the needle cover **908** to move proximally into the device **900**.

The needle cover **908** thus enters a position between the initial position and the activated position. During this initial movement, the deformable element **916** moves distally over the ledge feature **920**. Due to the shaped portion at the free end of the flexible arm, the deformable element **916** may be further flexed radially outwards during this initial movement. Once the needle cover **908** reaches an intermediate position, the free end of the deformable element **916** clears the ledge feature **920** and drops through the slot **920**, disengaging the carrier **914** from the needle cover **908**. In this manner, movement of the needle cover **908** from the initial position to an intermediate position causes the deformable element **916** to be deformed from the first configuration to the second configuration.

The deformable element **916** is in a relaxed state in the second configuration. The deformable element **916** may be referred to as a permanently deformable element or irreversibly deformable element, since in some examples after the element is deformed, the deformation cannot be reversed. In this embodiment, the deformable element **916** cannot be flexed so as to engage with the ledge feature **920**. The deformable element **916** remains in this second configuration for the remainder of the activation movement and throughout device removal. In this example, no part of the deformable element **916** is in contact with the needle cover **908** and thus the deformable element **916** does not exert any normal or friction force on the needle cover **908** in this position. The activation force on the needle cover **908** required after the intermediate position is reached is therefore reduced compared to prior art devices.

The deformable element **916** may produce a sound when it deforms from the first configuration to the second configuration, for example a snapping sound. This may be used to provide feedback to a user or to a sensor within the device **900** or attached to the device **900**. The snap sound may be produced by the free end of the deformable element **916** striking another component of the device **900** as it deforms.

Alternatively, or in addition, the deformable element **916** may be configured to produce a vibration when deforming from the first configuration to the second configuration. Again, this may be used to provide feedback to a user or to a sensor within the device **900** or attached to the device **900**. The vibration may be produced by the free end of the deformable element **916** striking another component of the device **900** as it deforms.

After the medicament has been delivered, during removal of the device **900**, the movement of the needle cover **908** is reversed, but the deformable element **916** remains in its second configuration.

Referring to FIG. **10**, a force profile graph **1000** is shown illustrating the force profile of a first device **110** and a second device **500**, **700**, **800**, **900**. The horizontal axis is the displacement of the needle cover is millimeters (mm) and the vertical axis is the user applied force in Newtons (N).

The first trace **1002** shows the force profile of the activation force of the first device **110** when the user is pushing the device **110** onto their body. The second trace **1004** shows the force profile of the activation force of the medicament delivery device **500**, **700**, **800**, **900**, when the user is pushing the device onto their body. The third trace **1006** shows the force profile of the device **110** when the user is removing the device **110** from their body. The fourth trace **1008** shows the force profile of the medicament delivery device **500**, **700**, **800**, **900**, when the user is removing the device from their body.

First arrow **712** indicates the difference in activation force between the device **110** and the medicament delivery device **500** during initial movement of the needle cover away from the pre-use position. The lower activation force (of approx. 0.5 N) is achieved by using a spring of lower force to bias the needle cover. The force of the spring is chosen to overcome the frictional forces on the needle cover and cause it to return to the pre-use position when it is removed from the body. As the friction forces in the medicament delivery device **500** as reduced due to the presence of the second slots **602** and relaxed position of the resilient member **516** in the intermediate and activated positions, a weaker spring can be used.

Arrow **1010** indicates the difference in activation force between the device **110** and the medicament delivery device **500**, **700**, **800**, **900** during movement between the intermediate position (occurring at approximately the end of the initial force spike) and the activated position (maximum displacement of the needle cover). The difference is approximately 1 N. As previously mentioned, a spring is used to bias the needle cover in a distal direction relative to the carrier. The force of this spring is chosen to overcome the frictional forces on the needle cover and cause it to return to the pre-use position when it is removed from the body. As the friction forces in the medicament delivery device are reduced due to the use of the deformable element, a weaker spring can be used. This may account for approximately half of the overall reduction in activation force required. The other half of the reduction is accounted for by the lack of friction forces between the carrier and the needle cover after the deformable element has transitioned to the second configuration.

The removal force profile of the medicament delivery device differs from that of the other device at the end of the removal movement, where the resilient member(s) **304** of the carrier **300** re-engage the slots **400** and cause a force spike. This force spike is eliminated in the devices **500**, **700**, **800**, **900** described above because the deformable element remains in the second configuration after the intermediate position during activation.

The terms "drug" or "medicament" are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient ("API"), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (SIRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

The drug or medicament may be contained in a primary package or "drug container" adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage (e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20° C.), or refrigerated temperatures (e.g., from about −4° C. to about 4° C.). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately, one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described

in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms "analogue" and "derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as "insulin receptor ligands". In particular, the term "derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g., a fatty acid) is bound to one or more of the amino acids. Optionally, one or more amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide.

Examples of insulin analogues are Gly (A21), Arg (B31), Arg (B32) human insulin (insulin glargine); Lys (B3), Glu (B29) human insulin (insulin glulisine); Lys (B28), Pro (B29) human insulin (insulin lispro); Asp (B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala (B26) human insulin; Des (B28-B30) human insulin; Des (B27) human insulin and Des (B30) human insulin.

Examples of insulin derivatives are, for example, B29-N-myristoyl-des (B30) human insulin, Lys (B29) (N-tetradecanoyl)-des (B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des (B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl-ThrB29LysB30 human insulin; B29-N—(N-palmitoyl-gamma-glutamyl)-des (B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des (B30) human insulin (insulin degludec, Tresiba®); B29-N—(N-lithocholyl-gamma-glutamyl)-des (B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des (B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®), Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide/HM-11260C (Efpeglenatide), HM-15211, CM-3, GLP-1 Eligen, ORMD-0901, NN-9423, NN-9709, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091 March-701, MAR709, ZP-2929, ZP-3022, ZP-DI-70, TT-401 (Pegapamodtide), BHM-034. MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Tirzepatide (LY3298176), Bamadutide (SAR425899), Exenatide-XTEN and Glucagon-Xten.

An example of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia or RG012 for the treatment of Alport 28yndrome.

Examples of DPP4 inhibitors are Linagliptin, Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine.

Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, and Goserelin.

Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F **20** (Synvisc®), a sodium hyaluronate.

The term "antibody", as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab')2 fragments, which retain the ability to bind antigen.

The antibody can be polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix complement. In some embodiments, the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

The terms "fragment" or "antibody fragment" refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited to such cleaved fragments. Antibody fragments that are useful in the devices and methods disclosed herein include, for example, Fab fragments, F(ab')2 fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, nanobodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin fusion proteins, camelized anti-

bodies, and VHH containing antibodies. Additional examples of antigen-binding antibody fragments are known in the art.

The terms "Complementarity-determining region" or "CDR" refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term "framework region" refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences, and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen.

Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

An example drug delivery device may involve a needle-based injection system as described in Table 1 of section 5.2 of ISO 11608-1: 2014€. As described in ISO 11608-1: 2014 (E), needle-based injection systems may be broadly distinguished into multi-dose container systems and single-dose (with partial or full evacuation) container systems. The container may be a replaceable container or an integrated non-replaceable container.

As further described in ISO 11608-1: 2014 (E), a multi-dose container system may involve a needle-based injection device with a replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user). Another multi-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user).

As further described in ISO 11608-1: 2014 (E), a single-dose container system may involve a needle-based injection device with a replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation). As also described in ISO 11608-1: 2014 (E), a single-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation).

Those of skill in the art will understand that modifications (additions and/or removals) of various components of the embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

The invention claimed is:

1. A medicament delivery device comprising:

a body;

a needle for injecting a medicament, the needle disposed at a distal end of the medicament delivery device;

a needle cover axially movable relative to the body between an extended position, in which a distal end of the needle cover is distal to a distal end of the needle, and a retracted position for dispensing the medicament from the medicament delivery device, wherein when the needle cover is in the retracted position the distal end of the needle is distal to the distal end of the needle cover; and

a carrier configured to support a syringe, wherein the carrier is disposed within the needle cover and comprises a deformable element, the deformable element being configured to change from a first configuration in which the deformable element is engaged with the needle cover to a second configuration in which the deformable element is not engaged with the needle cover,

wherein the deformable element is configured

to have a convex shape which protrudes from the carrier towards the needle cover when the deformable element is in the first configuration; and

to have a concave shape which curves away from the needle cover when the deformable element is in the second configuration,

wherein the carrier includes a recess configured to receive at least a part of the deformable element when the deformable element is the concave shape.

2. The medicament delivery device of claim **1**, wherein the deformable element is in the first configuration when the needle cover is in the extended position, and the deformable element is in the second configuration when the needle cover is in an intermediate position between the extended position and the retracted position.

3. The medicament delivery device of claim **2**, wherein the medicament delivery device is configured such that movement of the needle cover from the extended position to the intermediate position causes the deformable element to be deformed from the first configuration to the second configuration.

4. The medicament delivery device of claim **1**, wherein the needle cover comprises a cooperating element, and the deformable element is configured to (i) engage with the cooperating element when the deformable element is in the first configuration and to (ii) be disengaged from the cooperating element when the deformable element is in the second configuration.

5. The medicament delivery device of claim **4**, wherein the cooperating element comprises an aperture, a recess, a ridge, or a frictional surface.

6. The medicament delivery device of claim **4**, wherein the cooperating element comprises a slot, and the deformable element is configured to abut an edge of the slot when the deformable element is in the first configuration.

7. The medicament delivery device of claim **6**, wherein the medicament delivery device is configured such that movement of the needle cover proximally from the extended position causes the deformable element to disengage from the slot.

8. The medicament delivery device of claim 1, wherein the deformable element is configured to produce a sound when changing from the first configuration to the second configuration.

9. The medicament delivery device of claim 1, wherein the deformable element is configured to produce a vibration when changing from the first configuration to the second configuration.

10. The medicament delivery device of claim 1, wherein the deformable element is configured to be deformed from a first shape of the first configuration to a second shape of the second configuration.

11. The medicament delivery device of claim 1, wherein the deformable element is in a stressed state when the deformable element is in the second configuration.

12. The medicament delivery device of claim 1, wherein the deformable element is in a stressed state when the deformable element is in the first configuration.

13. The medicament delivery device of claim 1, wherein there is a zero normal force between the deformable element and the needle cover when the deformable element is in the second configuration.

14. The medicament delivery device of claim 1, further comprising a spring configured to exert a force which biases the needle cover axially towards the distal end of the medicament delivery device.

15. The medicament delivery device of claim 1, further comprising the syringe containing the medicament.

16. A medicament delivery device comprising:

a body;

a needle for injecting a medicament, the needle disposed at a distal end of the medicament delivery device;

a needle cover axially movable relative to the body between an extended position, in which a distal end of the needle cover is distal to a distal end of the needle, and a retracted position for dispensing the medicament from the medicament delivery device, wherein when the needle cover is in the retracted position the distal end of the needle is distal to the distal end of the needle cover; and

a carrier configured to support a syringe, wherein the carrier is disposed within the needle cover and comprises two or more deformable elements, the two or more deformable elements being configured to change from a first configuration in which each deformable element of the two or more deformable elements is engaged with the needle cover to a second configuration in which each deformable element of the two or more deformable elements is not engaged with the needle cover,

wherein each deformable element of the two or more deformable elements is configured

to have a convex shape which protrudes from the carrier towards the needle cover when each deformable element of the two or more deformable elements is in the first configuration; and

to have a concave shape which curves away from the needle cover when each deformable element of the two or more deformable elements is in the second configuration,

wherein the carrier includes a recess configured to receive at least a part of each deformable element of the two or more deformable elements when each deformable element of the two or more deformable elements is the concave shape.

17. The medicament delivery device of claim 16, wherein the needle cover comprises two or more cooperating elements, and each deformable element of the two or more deformable elements is configured to engage with a respective cooperating element of the two or more cooperating elements when each deformable element of the two or more deformable elements is in the first configuration and to be disengaged from the respective cooperating element when each deformable element of the two or more deformable elements is in the second configuration.

18. A medicament delivery device comprising:

a body;

a needle for injecting a medicament, the needle disposed at a distal end of the medicament delivery device;

a needle cover configured to be moved in a proximal direction into the body of the medicament delivery device to expose a distal end of the needle from a distal end of the needle cover; and

a syringe carrier disposed within the needle cover and comprising a deformable element,

wherein the deformable element is configured such that

prior to a movement of the needle cover relative to the body of the medicament delivery device, the deformable element has a first configuration in which the deformable element is engaged with the needle cover;

during an initial portion of the movement of the needle cover relative to the body, the deformable element is forced to deform into a second configuration by the movement of the needle cover such that the deformable element is not engaged with the needle cover; and

for a remainder of the movement of the needle cover relative to the body, the deformable element remains in the second configuration,

wherein the deformable element is configured

to have a convex shape which protrudes from the syringe carrier towards the needle cover when the deformable element is in the first configuration; and

to have a concave shape which curves away from the needle cover when the deformable element is in the second configuration,

wherein the syringe carrier includes a recess configured to receive at least a part of the deformable element when the deformable element is the concave shape.

19. The medicament delivery device of claim 18, wherein the deformable element is configured to permanently deform into the second configuration.

20. The medicament delivery device of claim 18, wherein the deformable element is configured to be deformed from a first shape of the first configuration to a second shape of the second configuration.

21. The medicament delivery device of claim 18, wherein the deformable element is in a stressed state when the deformable element is in the first configuration.

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